

# Inventory of Biotechnological Rules and Regulations in the MERCOSUR

ARGENTINA – BRAZIL – PARAGUAY - URUGUAY



This report has been elaborated by *Centro Redes* for the Biotech Program, within the scope of the "Diagnostic inventory of biotechnologies in the MERCOSUL and comparison with the European Union" contract (BIOTECH ALA-2005-017-350-C2).

The team of consultants who participated in this project was the following:

**Direction**

Mario Albornoz ([albornoz@ricyt.org](mailto:albornoz@ricyt.org))

**Technical Coordination**

Felipe Vismara ([fvismara@ricyt.org](mailto:fvismara@ricyt.org))

**Component 1: Capacities**

Coordinator: Lucas Luchilo ([luchilo@ricyt.org](mailto:luchilo@ricyt.org))

Consultants:

Isabel Bortagaray ([ib24@prism.gatech.edu](mailto:ib24@prism.gatech.edu))

Sergio Duarte ([gestec@conacyt.gov.py](mailto:gestec@conacyt.gov.py))

Mariano de Matos Macedo ([mariano@tecpa.br](mailto:mariano@tecpa.br))

Victor Romanowski ([vromanowski@gmail.com](mailto:vromanowski@gmail.com))

Federico Villarreal ([fv@agro.uba.ar](mailto:fv@agro.uba.ar))

Marcos Bilén ([mbilen@unq.edu.ar](mailto:mbilen@unq.edu.ar))

Mario Moreira ([m.moreira@tecpa.br](mailto:m.moreira@tecpa.br))

**Component 2: Legislation**

Coordinator: Juan Carlos Carullo ([jcarullo@fibertel.com.ar](mailto:jcarullo@fibertel.com.ar))

Consultants:

Fabiana Arzuaga ([fabianaarzuaga@fibertel.com.ar](mailto:fabianaarzuaga@fibertel.com.ar))

Katya Evaristo de Jesús- Hitzschky ([katiaregi@gmail.com](mailto:katiaregi@gmail.com))

Daniel Pagliano ([dpagliano@gmail.com](mailto:dpagliano@gmail.com))

**Component 3: Financing Instruments**

Coordinator: Ricardo Ferraro ([rferraro@fibertel.com.ar](mailto:rferraro@fibertel.com.ar))

Consultants:

Mariano de Matos Macedo ([mariano@tecpa.br](mailto:mariano@tecpa.br))

Thomas Otter ([tho@tigo.com.py](mailto:tho@tigo.com.py))

Silvia Peluffo ([apeluffo@csic.edu.uy](mailto:apeluffo@csic.edu.uy))

Verônica Beyreuther ([vbeyreut@fibertel.com.ar](mailto:vbeyreut@fibertel.com.ar))

**Component 4: Patents**

Coordinator: Rodolfo Barrere ([rbarrere@ricyt.org](mailto:rbarrere@ricyt.org))

Consultants:

Claudio Giacuzzo ([cgiacuzzo@gmail.com](mailto:cgiacuzzo@gmail.com))  
Sergio Duarte ([gestec@conacyt.gov.py](mailto:gestec@conacyt.gov.py))  
Isabel Bortagaray ([ib24@prism.gatech.edu](mailto:ib24@prism.gatech.edu))

**Component 5: Database**

Rodolfo Barrere ([rbarrere@ricyt.org](mailto:rbarrere@ricyt.org))  
Lautaro Matas ([lmatas@ricyt.org](mailto:lmatas@ricyt.org)).

# **Table of Contents**

## **1. Introduction**

### **1.1. Biotechnology regulation**

### **1.2. Component purpose**

## **2. Main issues**

### **2.1. The regulation of biosafety**

### **2.2. Regulation of biotechnological inventions**

### **2.3. Biotechnology and human health**

### **2.4. Information, participation and labeling**

### **2.5. Protection and access to genetic resources**

### **2.6. Biotechnology regulation in the MERCOSUR**

### **2.7. National policies, plans and strategies**

## **3. MERCOSUR Comparative Study**

### **3.1. Institutional Aspects**

### **3.2. GMO in the agricultural and food-related sector**

### **3.3. Regulation of intellectual property**

### **3.4. Biotechnology applied to human health**

### **3.5. Biotechnology and the Environment**

### **3.6. Biological diversity and genetic resources**

### **3.7. Information, participation and labeling**

### **3.8. Policies to promote biotechnology**

## **4. Institutional Framework in the MERCOSUR**

## **5. Conclusions and recommendations**

### **5.1. Situation and experience of each country**

### **5.2. Priorities arising in the MERCOSUR**

### **5.3. Importance of the EU contribution**

## **Annex I: Argentina**

## **Annex II: Brazil**

## **Annex III: Paraguay**

## **Annex IV: Uruguay**

# 1. Introduction

## 1.1. Biotechnology regulation

Biotechnology is a horizontal technology with the potential capacity to influence almost every sector of human activity. Health and mining, agriculture and the elaboration of drugs, the production of power or the elimination of polluting waste are, just to mention a few, some of the activities in which biotechnology has a significant incidence potential. This characteristic presents it as one of the most significant and relevant technologies from both the economic and social point of view. It is not a surprise that biotechnological development constitutes a priority of the scientific and technological policies.

Although the importance and economic potential of biotechnology are enormous, it should also be pointed out that, as it is a technology that “deals” directly with live organisms, it has a powerful symbolic value. Both aspects enable that the biological development has particular and revolutionary effects in the social and economic conformation of the 20<sup>th</sup> Century society. Therefore, it is not a coincidence that although the countries are interested in stimulating the industrial development of biotechnology, they also consider it necessary to set forth the proper regulations. Some of the main issues regarding the regulation of biotechnology are the following:

- a) Environmental matters related to the possible effects of dissemination of GMO (genetically modified organisms).
- b) Legal aspects regarding the limits of intellectual property rights;
- c) Ethical aspects related to human life, medical diagnosis, research in human embryos or human genome sequencing;
- d) Matters related to the formation, information and citizenship participation in the decision making process and the election of alternatives regarding biotechnology.
- e) Matters related to the conservation and sustainable yield of the biological diversity and the different contributions of biotechnology.

Within the MERCOSUR region, biotechnology applications have gained an increasing economic relevance, especially in the agricultural sector. Several countries of the group are important producers of Genetically Modified Organisms (GMO) and some of the main exporters of transgenic crops in the international market. This increases the use of new vegetal material, which leads to consider in a more significant manner the impacts on the environment and health, and to see that the new varieties are properly protected so as to safeguard the legitimate rights of the producers and thus enable an adequate context which allows to finance research, technical development and innovation in this sector.

In recent years, several countries of the region have increased their capacity to use the resources of modern biotechnology for the improvement of their industrial supplies. Medical biotechnology significantly grows for the production of new drugs, diagnosis methods and therapies and the emergency of research topics, such as stem cells, which position biotechnology as the center of their interest. Furthermore, the debate on the importance of biotechnology for the sustainable economic yield of the rich biological biodiversity which characterizes the region also increases. This progress in the application of biotechnologies is

developed in an every time more complex context which includes inevitable elements to be brought to the discussion of the rules and provisions for the regulation of biotechnology in the MERCOSUR. An important factor is the approval of the Cartagena Protocol on biosafety, which regulates the movement of GMO across borderlines and increases the pressure to set forth proper national rules, thus adding more complexity due to the conceptual and methodological controversies and the costs involved. It is important to enhance that these issues have been introduced in the discussions regarding the MERCOSUR organization. After several years of postponement of the treatment of this matter, which was originally related to the decisions made within the context of the Codex Alimentarius, the Southern Common Market created an "Ad-Hoc" Group on Agricultural Biotechnology (GAHBA, according to the Spanish acronym), which sets forth Negotiation Guidelines aiming to coordinate the Regulation Frameworks on biosafety and the commercial approval of GMO and to analyze the influence of labeling food derived from agricultural biotechnology.

## **1.2. Component purpose**

The component oriented its activities to identify and analyze rules and regulations referring to the structure and experience of the institutional frameworks which regulate biotechnology in the different economic sectors, the capacities and management experience, the environmental emerging consequences, biosafety, regulation of intellectual property and the economic and social problems involved, such as labeling, information to the public and consumer protection. Public policies and the programming of governmental institutions to influence the development of biotechnology are also included, as they were not considered in other components. The survey was based on the consultation of primary and secondary sources. The study included provisions contained in national constitutions, laws passed by national congresses, regulations of the executive powers and resolutions and provisions issued by ministries, organs and public decentralized institutions responsible for the promotion and regulation of the biotechnological activity. This approach, of national orientation, includes provisions of provinces and districts of the countries with a federal system of government. There is also an analysis of rules and minutes of MERCOSUR meetings.

The results obtained to date allow to count on a Catalogue of Rules and Regulations, Policies, Strategies and Plans applicable to the biotechnology area in the four countries, a commented list on the identified rules and regulations and a national report on the regulation processes. The studies contribute with an overview on the following:

- ⇒ Main characteristics of the institutional systems, technical, organizational and procedural aspects of the countries in the biotechnological area.
- ⇒ Regulations regarding confined research, release into the environment and commercial use of GMO in the agricultural sector (vegetal and animal).
- ⇒ Evaluation of the innocuousness and commercial release of food derived from GMO and/or which use GMO for its elaboration and qualities attributed.
- ⇒ Protection of intellectual property through the industrial property system and the system of protection of plant varieties.
- ⇒ Application of biotechnology in human health topics, including medication, clinical research, genic therapy, diagnosis reagents and experiments with stem cells.

- ⇒ Protection of biological diversity and access to genetic resources.
- ⇒ Public information and participation, and labeling of GMO.
- ⇒ Public policies, strategies and plans to promote biotechnology in the countries.

The project purpose is to contribute to the improvement of the regulatory processes of MERCOSUR countries and to favor the progress of regulatory harmonization, as well as the increase of commerce and research within the region.

## **2. Main issues**

### **2.1. The regulation of biosafety**

Among the fundamental matters regarding biotechnology regulation, biosafety is a crucial issue. As to the biotechnological aspect, biosafety embraces regulations, assessment actions and measures, monitoring, control and prevention in the execution of activities with GMO so as to reduce risks in the application of techniques and supplies to human and animal health, feeding, productive systems, the environment and biological diversity. Provisions also regulate technology trade and transfer, the setting of local parameters and their compatibility with international standards and practices.

The issue of biotechnology biosafety is a matter of serious controversy in the international scenario. The applications of biotechnology in general and the generalized use of DNA techniques, which contribute to achieve a better life quality in the planet, awoke the awareness of researchers, government officials, businessmen and society organizations on the importance of properly regulating the development and use of GMO.

The development of GMO at the laboratory does not present any difficulties; and there are standard methods and proceedings which adequately guarantee the safety of the operator and his environment. The small-scale reproduction of GMO is generally performed in highly isolated physical environments, in which minimum or top security conditions are guaranteed. The standards of European or American good production practices (GPP) and good manufacturing practices (GMP) are explicit and solid enough in terms of personal and environmental biosafety. The release of GMO into the environment is an extremely important issue due to the commercial impact the products of modern biotechnologies are starting to have. Lots of plants and microorganisms, and more recently animals and proceedings for genic therapy in human beings, are beginning to burst out of the research and development labs, reason for which it is necessary to count on methods and proceedings which guarantee their innocuousness without detaining their progress. The high-scale release of GMO requires extreme caution and a careful assessment of the risk. The experience of developed countries shows that government regulations are indispensable for the operation of a modern economy. Developing countries usually lack the mechanisms, proceedings, provisions and qualified human resources necessary to apply efficient and self-sufficient regulations, and that implies an urgency to adopt an agenda on the matter, which can be supported by international cooperation.

#### **2.1.1. Regulation in developed countries**

The regulation of biotechnology biosafety in developed countries is organized through public processes, in which the public/private cooperation has a key role. The progress of rules and regulations is based on strategies which promote self-regulation of the industry and strengthening of the control capacity of the public sector. The rules have different levels of consistency and must combine scenarios directly related with the political, social and productive aspects involved in the considered sector.

The regulation of agricultural biotechnology is quite controversial and there are differences of criteria among the national actors and the countries, attributable to cultural reasons, to consumer perception and to the position in the international markets. The main differences

have their root in the organized regulatory systems and in the approaches based on the precautionary principle of the Biosafety Protocol of Modern Biology (Cartagena Protocol) of the Convention on Biological Diversity, and those based on the principles of "risk assessment and management" and "substantial equivalence", of American tradition, which constitute the framework of the International Treaty on Phytogenetic Resources for Food and Agriculture under the aegis of the World Trade Organization. Several countries have signed and ratified the Cartagena Protocol, but some others have not.

In the European Union, after a long period of *de facto* postponement, new Regulations 1829/2003 and 1830/2003<sup>1</sup> became in force in 2004 and the European Commission approved sweet Bt-11 corn and later on glyphosate-tolerant NK603 corn. The new regulations have a community-related nature and more rigorous technical requirements. These regulations have special importance in the labeling of all the products for which European producers have a choice to produce with or without GMO, but the cases in which it would be mandatory to inform consumers are not included.

The regulation of foods safety is also a controversial issue at international level. In 1962, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) jointly set forth the Codex Alimentarius Commission in order to coordinate the existing rules on foods safety and to create new rules of international nature. The Codex regulations are voluntary, but under the aegis of the World Trade Organization (WTO), and they are used as reference to judge whether the rules and regulations of a nation fulfill the requirements of the GATT/WTO. Upon the appearance of biotechnology, the Codex task has become more complicated and consensus still seems to be far.

The regulatory framework of human biotechnology is much less developed than that of agricultural biotechnology. The most relevant elements of this regulatory framework are the provisions regarding the areas of experiments with human beings and the approval of drugs. The evolution of the rules regarding experiments with human beings constitutes a case of effective application of ethical restrictions to scientific research, at both national and international level. The basic law is the Nuremberg Code, to a great extent replaced by the Declaration of Helsinki, of the World Medical Association, which emphasizes on self-regulation. Despite these regulations, research practices vary a lot in the developed nations.

## **2.1.2. Regulations in the MERCOSUR**

In developing countries there are only a few updated regulations on biosafety and the capacity of the governmental regulatory organisms which must address issues such as research, development, pre-trade trials, industrial production and commercialization of products derived from modern biotechnology are very scarce. The countries which do have a regulatory framework have adopted -with adaptations and predominantly-, the models used in the United States - United States Department of Agriculture (USDA) and Animal and Plant Health Inspection Service (APHIS) for plants, Federal Drug Administration (FDA) for biodrugs, and the Center for Disease Control and Prevention (CDC-NIH) for research and development.

During the last decade, some countries of the region started to implement measures to face the biosafety problem, emphasizing in the regulation of the release of GMO into the environment. The MERCOSUR countries have developed their regulation experiences using

---

<sup>1</sup> European Parliament and Council: Regulation 1830/2004, on traceability and labeling of GMO. Official Gazette of the European Union, September 22<sup>nd</sup>, 2003.

different principles, according to what happens with the matter in the international context. Argentina applies an approach inspired by the American tradition, based on the principles of “risk assessment and management” for considering environmental problems, and of “substantial equivalence” for food-related issues. Brazil, Paraguay and in the last years Uruguay, are oriented towards an approach of European inspiration, which privileges the “precautionary approach” of the Cartagena Protocol on Biosafety, with greater consequences for the evaluation of environmental impacts and foods safety. All the countries under study have created institutional structures to address the problems GMO biosafety. The experience of assessment of GMO products is relatively new in most of the countries. In several countries there are discussions between institutional actors, companies and social organizations. These discussions affect the possibility of passing laws on the matter, or make it difficult to apply already passed laws, thus generating controversy and lawsuits.

## **2.2. Regulation of biotechnological inventions**

Another important matter to be studied in the field of biotechnology regulations is that of intellectual property rights related to biotechnological inventions. Both the laws for the protection of patents and of protection of plant varieties have considered biotechnological innovations as an object of protection. Even though intellectual property legal systems have existed for more than a century, biotechnological patents date from the late seventies. The adoption on the part of national States of the TRIP regulations issued by the WTO has made of this law division one of the most harmonized at worldwide level; that also can be applied to the MERCOSUR, to the regulations regarding the protection of biotechnological innovations by means of patents as well as to plant varieties.

### **2.2.1. International situation**

From the adoption of the TRIP guidelines issued by the WTO on the part of the national patent legislations some basic system institutions were standardized with respect to procedural aspects, terms, basic patentability requirements, etc. However, remarkable differences still persist between the developed and the developing countries as to the scope of what is considered patentable in “living matter” and particularly to what refers to live beings “*as they are in nature*”. Directive 98/44 EC of the European Union, which regulates the legal protection of biotechnological inventions, has its parallel directive in the MERCOSUR countries; however, the “inventive activity” and the patenting of living matter are defined very differently. The reasons for this are quite varied, but we could basically restrict them to different status of development of the research and the biotechnological industry, as well as to the great biodiversity the MERCOSUR countries present.

The regulation of biodiversity and the its preservation, facilitating the sustainable development of science, technology and industry is also a fundamental issue. The Convention on Biological Diversity of Rio de Janeiro of 1992 was signed and ratified by a great number of countries; nonetheless, little progress has been made in the application of several of its statements. An example of it is the right to “sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. In order for this clause to operate, the patent offices should require the owner of a patent to evidence the origin of the genetic resource that was used for the invention and the access

permission granted by the competent authority. This is not taking place yet, despite the articulation attempts made by the CBD Secretariat and the WIPO. We shall revise the regulations referring to the protection of biodiversity, the access to genetic resources, the availability of said resources for research and the knowledge the countries have of their assets in terms of genetic resources. Finally, it is necessary to address the issue of regulations regarding research and use of stem cells in cellular therapies and regenerative medicine. The European Union has also issued regulations regarding the possibility of patenting these developments through Regulation 23d(c) and Directive 98/44, sections 5 and 6. The United Kingdom has generated its own regulations of patentability which set aside even the EPO directions.

## **2.2.2. Situation in the MERCOSUR**

In the MERCOSUR countries, the main means of legal protection are: a) invention patents; b) trade secrets; c) rights on plant varieties. In the case of biotechnology, there are specific problems regarding the patenting of living organisms and microorganisms and the situation is heterogeneous. There is uncertainty in several countries as to the admissibility of patenting plants and animals, and the positions taken by the WIPO and the GATT indicate a general attitude of caution or rejection as to said possibility. In most Latin-American countries it is not allowed to patent animal breeds and the biological proceedings for obtaining them; consequently, the issue remains at the discretion of the patent offices or the judicial courts.

The granting of biotechnological patents requires that the patent offices have the human capacity and the proper infrastructure for the analysis and release of the information contained in the patents. Patent database systems have been recently implemented in countries as Argentina and Brazil (regarding published and pending proceedings or granted patents) which can be accessed online through the Internet, as in the case of the European Patent Office system. As to the deposit of microorganisms, in the majority of the MERCOSUR countries, there are not any institutions acknowledged by the Budapest Convention to comply with the requirement of "sufficient description" of the invention. Another element to be taken into account is the time that it takes a patent to be processed and granted, which amounts to almost twice the time (8 to 10 years) in Latin-American countries –especially the countries of the MERCOSUR- compared to the European offices (4 to 5 years). The appearance of a new research and production paradigm related to biotechnology creates tensions and uncertainties in the legal system of inventions appropriation. The unclear limits between what is scientific and what is technological and the overlapping of companies and public laboratories in the same areas of research favor the release of knowledge and hamper its private appropriation. It can be noticed that the life cycle of new products becomes shorter, which reduces the possibility to recover R&D costs and to finance new developments.

The importance of patents increases in the pharmaceutical industry, as competition within that sector becomes more intense. The birth of a new research paradigm and the beginning of a new wave of biopharmaceutical innovations characterize the present situation of that industry. The new emerging industrial profile is based on a solid R&D component, while the great investments constitute an important barrier against the entrance of competitors. For the developing countries, patents are a complex issue and with less evident benefits. The protection of the breeders<sup>2</sup> rights was introduced in the Southern Cone countries. The

---

<sup>2</sup> Jaffe, W. and Van Wijk, J. *El Impacto de los Derechos de Obtentor en los Países en Desarrollo. Debate y Experiencia en Argentina, Chile, Colombia, México y Uruguay [Impact of Producer Rights in Developing*

explicit purposes were to promote the private activity of phyto-improvement and to increase the access to high-quality foreign varieties. The only type of protection of intellectual property rights of plant varieties applied in the Region is the Right of the Breeder of Plant Varieties<sup>3</sup>. To date, ten countries have signed the UPOV'78 Act and four are preparing their adhesion to the UPOV'91, due to the fact that the adhesion list for the 1978 Act has closed.

## 2.3. Biotechnology and human health

The regulation of biotechnology applied to human health includes the following: approval of new medication, trials with human beings, genic therapy, stem cells, etc. The progress of the regulatory process in this issue is very unequal, according to the considered country.

## 2.4. Participation, information and labeling

As to the labeling of food derived from GMO, there are different criteria in the international context. The countries which have adopted labeling regulations using mandatory or elective systems generally apply two different criteria.<sup>4</sup> The first criterion refers to the detection of DNA or protein derived from the transgenic process in food, as in the case of the European legislation and that of other countries. In this case, there are minimum or maximum levels of content in order to set forth the obligation to label or not, which influences the sampling and sensitivity of the required lab techniques. The second criterion is related to the product traceability. Some countries have a legislation which obliges to declare that the food may come from GMO or transgenic plants, which requires to have a traceability system. In this case the costs are higher, as it is necessary to have information on the ingredients and eventually on the additions or technology adjuvants applied to the food manufacturing process. Practice shows that controls are almost impossible, as much information must be contributed with by many agents. In Argentina there are no specific regulations for the labeling of food derived from GMO. It is not required to declare in the label that the product derives from GMO. However, some provinces and districts have passed laws on the matter.<sup>5</sup> In Brazil, the discussion ended up with the approval of a regulation on the matter, and in Uruguay a voluntary labeling system is about to be created.

---

*Countries. Discussion and Experience in Argentina, Chile, Colombia, Mexico and Uruguay*] BIOCIT, Electronic Bulletin of CIT of the UNAM, México D.F., 1997.

<sup>3</sup> Wendt, J. and Izquierdo, J.: *La Práctica del Acceso a los Recursos Genéticos y de los Derechos de Obtenciones Vegetales en América Latina*. [Practice of Access to Genetic Resources and Rights over Plant Varieties in Latin America]. FAO Regional Office for Latin America and the Caribbean, Santiago de Chile, December 13<sup>th</sup>, 2000.

<sup>4</sup> See Burachik (et al) ILSI-RNBio

<sup>5</sup> The Province of Chaco regulates transgenic products, their sale in supermarkets, the location of the products and consumer information; province of Tierra del Fuego has set forth that there must be information and publicity on the GM food; the District of San Carlos de Bariloche sets forth that any food resulting from the use of genetic engineering techniques for its production and/or process shall have to be identifiable through a list provided to shops by the municipal authority.

## **2.5. Protection and access to genetic resources**

Genetic resources constitute the raw material of biotechnology. In this area, the regulations regarding access and records/banks of genetic resources, appropriation systems and their use as well as the distribution of the earnings they generate are relevant. The most relevant international rule in this respect is the Convention on Biological Diversity, which has been ratified by the four MERCOSUR countries. Some countries face long discussions on this matter; in Brazil, they progress towards the update of the law which regulates the access to genetic resources, to the traditional knowledge associated thereto and the distribution of benefits arising therefrom by the local communities.

## **2.6. Regulation of biotechnology in the MERCOSUR**

The legal framework related to the MERCOSUR organization has special characteristics<sup>6</sup>, as no institutional and legal structure has been organized in order to allow the immediate incorporation to the national legislations of the agreements established at group level. The decisions of the Southern Common Market Council (CMC) and the Directives of the Trade Commission of the MERCOSUR are binding upon the States, but they must include them in their domestic legal systems. In practice, the incorporation of these regulations in the domestic systems is a slow process which has a different rhythm in every country.

There is no significant progress in the negotiation of the aspects related to the application of biotechnology. Despite of some institutional efforts and technical contributions directed to ease harmonization, there are no common regulations or proceedings. During several years the countries had agreed not to regulate GMO food until the negotiations concerning the Codex Alimentarius<sup>7</sup> were finished. But on a recent date, as already mentioned, they have organized an Ad-Hoc Group which progresses departing from exploratory studies, national profiles and comparative analyses.

It is important to enhance that there is progress in the regulation of the general context of some areas in which biotechnology has an important application: environment, veterinary, animal genetics, seeds, etc. The following are examples of the above mentioned progress: Framework Agreement on the Environment, Regulatory Framework of Animal Genetics of Bovines, Ovines, Equines and Swines in the MERCOSUR, Regulatory Framework for Veterinary Products and the MERCOSUR Standard of Seeds Technology.

## **2.7. National policies, plans and strategies**

---

<sup>6</sup> Zalduendo. *La propiedad intelectual en el MERCOSUR. [Intellectual Property in the MERCOSUR]* 2<sup>nd</sup> Intellectual Property Congress, University of Buenos Aires, Secretariat of Science and Technology; Science and Technology Series at the UBA, August 24<sup>th</sup> and 25<sup>th</sup>, 1998.

<sup>7</sup> See Dellacha, J., Carullo, J., Plonsky, G. and De Jesús, K.: Biotechnology regulation in the MERCOSUR.

Biotechnology is one of the interdisciplinary areas that due to its potential impact in the economic development of a country is recognized as a priority by the public policies of several countries of the region. In that sense, as there is a strong interest in regulating its applications seeking to guarantee environmental quality and human health, some countries have developed strategies to support the development of their national capacities on the matter, strengthening their R&D structures, supporting the development of basic research and its use on the part of companies in order to increase their competitiveness and to promote innovation.

That is why it is interesting to identify and analyze the promotion regulations and the national programs and strategies of public areas or institutions, the purpose of which is to strengthen the biotechnological capacities of the countries and ensure a greater economic and social impact of the applications of these technologies. In this respect, the component directly relates to the party responsible for the identification of biotechnology financing instruments in the MERCOSUR countries.

## 3. MERCOSUR comparative study

### 3.1. Institutional aspects

The analyzed set of regulations includes constitutional-level provisions, laws passed by the National Congresses, Decrees and other instruments issued by the National Executive Power of each country and Rules and Regulations and other instruments issued by the regulatory organisms of each country, including provincial and municipal provisions. The universe and institutional hierarchy of the rules have significant differences, according to the country being considered. The history of the development of the regulatory institutions is also very different, and long is the list of conflicts, interinstitutional disagreements and disputes over jurisdiction they have generated during the last years. The analyzed constitutional provisions are generally related to the issue of environmental protection and right to citizenship information. These rules are present in the Constitutions of all the countries of the group, but their translation into operational regulations has been rather limited, reason for which their impact on the regulatory system is relatively mild. That is the case of Argentina and Paraguay. In the case of Brazil, many of these issues have been taken to an operational level, through national laws which govern the matter. Uruguay is undergoing a transition and has a temporary system while it prepares the passing of a National Biosafety Law.

In Argentina, the regulation system has a long tradition in terms of biosafety of GM crops, animals and foods derived from GMO. Regulations are under the jurisdiction of the Secretariat of Agriculture, Livestock Breeding, Fishery and Food of the Ministry of Economy and Production. The regulations of highest hierarchy are the Resolutions of said Secretariat, accompanied by the Resolutions and Provisions of organisms depending thereof: the National Sanitation and Quality Service of Agricultural and Food Safety (*Servicio Nacional de Sanidad y Calidad Agroalimentaria* – SENASA, according to its Spanish acronym) and the Seeds National Institute (INASE, according to its Spanish acronym). In the health sector, regulations consist of Resolutions by the Ministry of Health and particularly the National Drug and Medical Technology Administration (ANMAT, according to its Spanish acronym).

As to the Environment, there is a strong legislative structure, with potential jurisdiction over biotechnological issues, which is reflected in the identified laws and decrees and in the regulations by the Secretariat of Environment and Human Development. However, in practice these instances have little intervention in concrete decisions. Argentina has made several attempts, of different origins and approaches, but to date it has not been able to pass an instrument to regulate biotechnology. This process has been linked in some cases to projects directed to ratify the Cartagena Protocol on Biosafety, instrument which Argentina has signed but has not ratified, arguing conceptual, economic and commercial grounds.

Brazil is the only MERCOSUR country which has a National Biosafety Law. Law No. 11105 sets forth the regulations and proceedings for the development, importation and commercial use of GMO. The law creates a national regulation framework integrated by: the Biosafety National Technical Committee (CTNBio, according to its Portuguese acronym), the National Biosafety Council (CNBS, according to its Portuguese acronym), the registration and control organs of the Ministries of Health, Environment and Agriculture, and of the Special Secretariat of Agriculture and Fishery, the Biosafety Internal Commissions (CIBio, according to its Portuguese acronym) R&D institutions and the Biosafety Information System.

In Paraguay, the use of transgenic material is analyzed within the general context of the country legislation. It applies international regulations, instruments and proceedings for risk assessment purposes and a case-by-case and step-by-step criterion. The institutional responsibility corresponds to the Ministry of Agriculture and Livestock Breeding (MAG, according to its Spanish acronym). The National Commission of Agricultural and Forestry Biosafety depends on said Ministry and is responsible for assessing the GM material in the agricultural and forestal environment -developed or to be introduced within the country- and for recommending the authorization of entrance of said material in the national territory according to the proposed use. Within its scope of actions, Risk Assessment Committees are organized for the main sectors of application of GMO, and its Technical Secretariats manage the release processes. The latter involve the intervention of the Ministry of Public Health and Social Welfare through the National Food and Nutrition Institute (INAN, according to its Spanish acronym) and the Ministry of Industry and Trade.

In Uruguay, Decree No. 468/2008 amends the regulatory framework regarding plants biosafety and their genetically modified parts. It creates an organic structure in plants biosafety, taking into account the future National Biosafety Law for GMO, set forth in Section 5 of Decree No. 37/007, of January 29<sup>th</sup>, 2007. The structure shall be formed by the following institutions: the Biosafety National Cabinet (GNBio, according to its Spanish acronym), the Risk Management Commission (CGR, according to its Spanish acronym), the technical/scientific instance of Risk Assessment in Biosafety (ERB, according to its Spanish acronym), the Institutional Articulation Committee (CAI, according to its Spanish acronym) and the Consulting Committee of Biosafety (CCB, according to its Spanish acronym). The GNBio is presided by the Minister of Livestock Breeding, Agriculture and Fishery, the Minister of Public Health, and the Ministers of Economy and Finance; Dwelling, Territorial Organization and Environment; Foreign Affairs; Industry, Power and Mining. The CGR is formed by a delegate of the Ministers who are part of the GNBio and operates as advisor for the Executive Power regarding plant biosafety and the proceedings for their assessment, public consultation, follow-up and monitoring, handling and penalties, etc.

## **3.2. GMO in the agricultural and food-related sector**

The MERCOSUR countries have different approaches for the regulation of biosafety of GMO, aligned with the situation of that same issue in the international context. All the countries use risk assessment proceedings and fulfill –although with different national capacities- the internationally accepted rules and practices. This characteristic makes the biosafe use of GMO in the region possible. This situation changes and becomes more complex when the regulations and proceedings related to the commercial release of GMO are analyzed and compared. The main characteristics of the systems in the countries are analyzed in the next paragraphs.

### **3.2.1. Processes for the commercial release of GMO crops**

In Argentina, in order to be granted an authorization for the commercial cultivation of a GM plant, it is necessary to have an authorization issued by the SAGPyA to execute tests under controlled conditions with a positive evaluation by the CONABIA. After the tests, it is necessary to have a CONABIA approval which shows that the test effects in the agricultural

and ecosystem do not differ significantly from those that the non-GM homologous would cause. A positive evaluation rendered by the CTAUOGM –a SENASA division- is also necessary regarding the suitability of food derived from GMO for human and animal consumption. An evaluation by the DNM – a SAGPyA division- on the impact the GMO may have on the international trade of Argentina's agricultural products is also needed. Once the tests are approved by the CONABIA, the CTAUOGM and the DNM, the Secretary of Agriculture, Livestock Breeding, Fishery and Food issues -or not- the permission for marketing the GMO. Crops are registered with the INASE and surveillance and monitoring of the released material are under the responsibility of the INASE and the SENASA. The decisions resulting from this process are under the responsibility of the SAGPyA, with the technical support of the CONABIA.

In Brazil, the authorization for the cultivation of GMO at commercial level requires a favorable decision on the part of the CTNBio, a collective body related to the MCT, regarding the GMO biosafety for human, animal and plant health and for the environment. The technical decision issued by the CTNBio is binding upon the other administrative divisions, as to the risk assessment aspects. Once the favorable decision of the CTNBio is obtained, the registration of the GM cultivars must be requested before the Cultivar National Registry (RNC, according to its Portuguese acronym) of the Ministry of Agriculture, Livestock Breeding and Supply in order to obtain the authorization for the GMO to be traded. In the event the CTNBio understands that the commercial release of a GMO may potentially or effectively cause environmental degradation, a prior environmental license is required, which is issued by the IBAMA, related to the Ministry of Environment. At the request of the CTNBio, the CNBS may be called to issue an opinion on the convenience aspects and the social and economic opportunity and/or national interest originated with the GMO release.

In Paraguay, the MAG grants the authorization for the commercial release of the genetic transformation event, based on the biosafety, food innocuousness, animal suitability, commercial convenience and environmental license aspects processed by the Commission of Agricultural and Forestry Commission. The Ministry of Public Health and Social Welfare, through the National Institute of Foods and Nutrition (INAN, according to its Spanish acronym), coordinates the evaluation of the food suitability of the GMO, according to their proposed use. The Ministry of Industry and Trade, through the Vice-Minister of Trade, analyzes the convenience and opportunity for the commercial release of the GMO and their derivatives, taking into account the positioning of GMO products under study in both the national and the international markets. MAG's authorization is effected before to the inclusion of the material in the Commercial and/or Protected Cultivar National Registries. Monitoring of the biosafety conditions of the GMO introduction shall be under the responsibility of the registration and control entities: SENAVE, SENACSA; MSPyBS -INAN and SEAM, or other technical pertinent institutions, according to their jurisdictional environment.

In Uruguay, the GNBio authorizes the new requests regarding vegetables which enter the country and defines the guidelines of the national biosafety policies for vegetal GMO. The decision on the approval of new crops corresponds to the CGR and the evaluation of the requests to the ERB, with the advisory participation of the CAI. Follow-up and control is under the responsibility of the specialized inspection bodies of the Ministries which form the Biosafety National Cabinet (GNBio).

### **3.2.2. Biosafety of crops derived from GMO**

All of the MERCOSUR countries have developed institutional structures to assess the release of GMO crops. The mechanism basically consists in the creation of Commissions formed by experts, who perform evaluations and render opinions for the decision making of

ministries, secretariats or other institutions responsible for the adoption of administrative decisions. The Commissions differ in several significant aspects, among which it is important to mention the following: their competences on the different productive areas to which GMO are incorporated and their location and institutional hierarchy in the respective countries. But the most significant difference lies in the principles that prompt them, the level of complexity of the national systems and the accumulated regulation experience.

In Argentina, the CONABIA has technical competence regarding vegetable and animal GMO and the CTAUOGM -a SENASA division-, intervenes to assess the food-related innocuousness of the GMO to be released. Both Commissions forward their recommendations to the SAGPyA. The CONABIA functions are to provide assistance to the SAGPyA on the technical and biosafety requirements that the genetic material obtained through biotechnological proceedings must comply with prior to their incorporation –by any proceedings or means and in any character whatsoever- into the biosystem, propose regulations and issue opinions in areas of its competence.

The CONABIA has elaborated specific regulations regarding technical and biosafety requirements that the experiment and/or release of vegetal or animal GMO must comply with, which are incorporated through Resolutions by the SAGPyA. The assessment of the impact of the GMO commercial release on international markets is under the responsibility of the Markets National Direction, which informs on the convenience of trading GM crops considering their impact in the export markets of the country. For that matter, it performs internal studies on the market situation and consults with other public and private actors on the technological and quality aspects of the proposed innovations.

The CONABIA is formed by representatives of institutions involved with agricultural biotechnology of the public and private sectors. In the public sector, National Research Institutes, Universities and the Secretariat of Sustainable Development and Environmental Policy and the Secretariat of Health were represented. The private sector used to participate through different associations linked to agricultural and food-related biotechnology. Its present composition includes 21 representatives, who decide by a simple majority. The CTAUOGM is formed by representatives of the CONABIA, National R&D Institutes and Chambers from the Agricultural and Food-related sector of the country.

In Brazil, the Biosafety National Technical Commission (CTNBio) is responsible for the technical regulation of biosafety; the commission acts within the institutional framework of the Ministry of Science and Technology. The CTNBio is formed by qualified members appointed by the Ministry of Science and Technology, by renown scientific specialists in matters such as consumer defense, health, environment, biotechnology, family agriculture and occupational health, who are appointed by the Ministries with institutional responsibility over those issues.

The CTNBio has technical jurisdiction over the activities related to GMO of all the areas. It performs its tasks in combination with the Ministries of Environment, Health and Agriculture which, from the technical opinion of the CTNBio, processes the decisions through its own monitoring divisions, pursuant to their specific competences. The evaluation of foods derived from GMO approved by the CTNBio then pass through the Health Biosafety Commission (CBS, according to its Portuguese acronym), of the Ministry of Health. Said Commission, at the request of the CTNBio, assesses the processes regarding commercial release requests of genetically modified food.

The CTNBio sets forth –within the scope of its performance- criteria for the risk assessment and management of GMO and their derivatives; it performs risk assessments on a case-by-case basis, authorizes, registers and follows-up R&D activities with GMO and their derivatives, defines the biosafety level and classifies the GMO according to the type of risk,

technically supports the competent organs in the accident and disease prevention process and controls their activities. It further has police power for the identification of activities and products which apply GMO or their derivatives and which may cause environmental degradation or may imply risks to human health.

The Law grants powers to the CTNBio to set forth regulations on research activities and projects related to GMO and their derivatives. Through Normative Regulations, it issues Biosafety Quality Certificates (CQB, according to its Portuguese acronym) and regulates the creation of Internal Biosafety Commissions (CIBio, according to its Portuguese acronym) for all the institutions which wish to develop activities involving GMOs and/or their derivatives.

In Paraguay, the Agricultural and Forestry Biosafety Commission, which depends on the Ministry of Agriculture and Livestock Breeding, is the institution empowered to authorize activities which can be performed with GMOs in all the productive sectors of the country. It is formed by representatives of offices belonging to the Ministries of Agriculture and Livestock Breeding, Public Health and Social Welfare, Industry and Trade. It is also formed by the SENAVE, the SENACSA, the Secretariat of Environment (SEAM, according to its Spanish acronym) and the Schools of Agricultural Science, Veterinary and Exact and Natural Science of the University of Asunción. Within the Commission there shall be a Risk Assessment Committee, a Committee for the Assessment of Food Suitability, a Committee for the Evaluation of Animal Suitability and other committees for the treatment of specific issues.

Among its powers, it issues a decision regarding the introduction, field tests and release of GM material into the environment, advocating for the fulfillment of safety measures related to the use, manipulation and release of GMO into the environment, in a manner compatible with the productive needs, environmental protection and human health. It also sets forth the risk monitoring criteria of the GMO and their derivatives and provides technical support to the competent authorities in charge of monitoring. Furthermore, it proposes biosafety regulations, contingency plans in cases of accidents, biosafety measures in case of non-fulfillment of the rules and issues opinions in the areas of its scope of action.

In Uruguay, the Biosafety Risk Assessment (ERB, according to its Spanish acronym), is an instance formed by a small number of specialists with professional skills who are qualified to act in the different areas involved in risk assessment. They are proposed by the CGR and appointed by the GNBio. Each Risk Assessment is coordinated by an ERB technician, according to the event to be assessed. Its purposes are to assess risk on a case-by-case basis, based on objective scientific grounds; identify capacities, design Risk Assessment protocols for the environment, human health, animal and vegetal sanity, issue communications to the advisory instance which are later on disclosed to the public. The assessment may include an additional instance, through the intervention of the Institutional Articulation Committee (CAI, according to its Spanish acronym), a technical and scientific stage of the Risk Assessment process, formed by the GNBio Ministries and by divisions of the Biological Research Institute Clemente Estable, the University of Uruguay, the Uruguay Technological Lab, the National Institute of Agricultural Research, the Seeds National Institute and the Pasteur Institute, which approved –within the scope of their institutions- the necessary protocols for Risk Assessment. The CAI shall issue a non-binding opinion at the request of the ERB, and shall be called and coordinated by the ERB technician in charge of each case, submitting the results before the ERB, which shall be presented before for the CGR for its consideration.

### **3.2.3. Risk assessment and management of GMO**

Regulations regarding GMO releases into the environment are based on practices which tend to reduce the possibility of causing incidents and minimize eventual damage. That is why rules and regulations based on the assessment and management of risk have been set forth. Risk assessment implies to systematically gather the information available on the GMO and on the potential risks it may involve, in order to have an opinion on them, identify the danger to be assessed and the effect of the response to exposure. It is a theoretical exercise based on empirical data.

The handling or management of risk consists in a selection process of the proper policies and the regulatory action, integrating the results of the risk assessment with social, economic and political decisions. It is convenient to divide the process into stages: one with a prior description as detailed as possible of the GMO and another with the release purpose. The quality of every risk assessment shall depend on the degree of knowledge of the GMO and the expected effects. In Argentina, according to the GMO characteristics, the following issues are analyzed:

- ⇒ Description of the molecular biology of the donor-vector-receptor system
- ⇒ Transformation method used
- ⇒ Main genes (and their donor organisms). Ancillary genes (selection markers).
- ⇒ Regulatory sequences (promoters, terminators, enhancers, etc.). Other genetic elements included.
- ⇒ Expression products, plant tissue in which they are expressed, levels of expression. Sequence homology with toxic or allergenic proteins.
- ⇒ Phenotypical description of the receptor organism, origin centers or genetic diversity.
- ⇒ Phenotypical stability and number of generations in which it was verified.

The requested information depends on the scale of the release: from the lab/greenhouse up to field tests. For the events awaiting a commercialization authorization in the country, a specific protocol for being granted the authorization must be submitted. In all the cases the applicant must provide information on basic aspects of the biosafety proceedings.

In Brazil, a description of the GMO is also required, as well as the danger it entails, that is to say, the situation in which under certain circumstances its release could cause damage. In general, the following situations could arise:

- ⇒ Transfer capacity of the genetic material.
- ⇒ Phenotypic and genetic instabilities.
- ⇒ Pathogenicity, toxicity and allergenicity.
- ⇒ Survival, settling and dissemination potential.
- ⇒ Other negative effects over organisms not established as target.

Annex IV of the Biosafety Law describes the recommendations of the "Risk Assessment for the Environment" of GMO, detailed as follows:

- i. plants;
- ii. microorganisms;
- iii. microorganisms associated to animals;
- iv. microorganisms associated to plants;
- v. organisms used for biological control;
- vi. organisms for bioremediation;
- vii. vertebrate animals (excluding fish);
- viii. fish and other organisms of aquatic life
- ix. invertebrate animals

In Paraguay, the Agricultural and Forestry Biosafety Commission exclusively performs the GMO risk assessment of all the sectors. The assessment must be performed based on the following:

- a) risk assessment shall be performed in a transparent and scientifically competent manner, taking into account the opinion of experts and the guidelines elaborated by the pertinent international organizations such as CODEX, OIE, CIPF, FAO and other.
- b) Possibilities of escapes, genetic escapes, pollen spread, genetic stability of the testing material, movement of insects and other technical variables.
- c) The agricultural ecosystem in which the field test of the GMO shall be performed.
- d) Biological characteristics of the organism.
- e) Existence of related plants located in active germplasm banks of the area.
- f) Consequences of the potential settling and persistence in the agricultural/ecosystem in the area and possible detriment to other organisms of the environment.
- g) Pathogenicity, toxicity and allergenicity for human beings and other organisms.
- h) Capacity to transfer genetic material and paths of potential spread.

Rules and regulations in Uruguay are undergoing an update process, within the scope of a new set of laws passed during 2008. The immediate precedent has an approach which includes the study of the organism properties, their potential to cause genetic changes in populations and the monitoring and control of the accessible environment. In order to state the environmental safety level, risks against human health and natural ecosystems are taken into account, as well as the capacity to manage the introduction and control in a planned manner, so that the test can be conducted in a safe way. Furthermore, the history of adverse effects in an accessible environment and similar effects, the potential to turn into a harmful organism and the survival possibilities after the test are also included.<sup>8</sup>

An analysis of the organism and the molecular biology of the donor-receptor-vector system used for the production of the genetically modified plant is performed, as well as the location where all of them have been produced, the purpose of the introduction and, most importantly, a detailed description of the biosafety methods and proceedings proposed. Should it be pertinent, the destination of the grown products, the plots of land dealt with and their future uses and subsequent controls are also requested. Information must have a scientific nature, and should be grounded, published and judged. The application for that organism in particular must be considered.

### **3.2.4. Foods derived from vegetal and animal GMO**

For the assessment of food products derived from GMO, the concept of "Substantial Equivalence" has been introduced, according to which if food derived from biotechnology can be characterized as an equivalent of its conventional predecessor, it can be supposed that it does not pose new risks and therefore, it is acceptable for consumption. Should there be any differences, additional tests are conducted.

In Argentina, the Technical Advisory Committee on the use of GMO -a SENASA division- sets forth the suitability for human and animal consumption of food derived from vegetal GMO, applying Regulation SENASA No. 412/2002. This Committee is formed by representatives of the public sector, the private sector (including producers, transformers and

---

<sup>8</sup> Secretariat of Agriculture, Livestock Breeding, Fishery and Feeding (SAGPyA). *Bioseguridad Agropecuaria: Hacia la comercialización de vegetales y vacunas genéticamente modificados [Agricultural Biosafety: Towards the commercialization of genetically modified plants and vaccines]*. SAGPYA, Buenos Aires, September, 1997.

distributors) and by representatives of scientific and academic institutions. The evaluation is carried out in a thorough manner, by means of the application of the risk assessment procedure, based on the concept of substantial equivalence. The SENASA analyzes the following:

- a) Expression products: characterization and concentration.
- b) Nutritional facts: composition, nutritional effects associated to genetic modification, alteration of nutritional properties or any other non desired effect which could be produced due to genetic insertion.
- c) Direct effects on health: identification of toxic substances, specific components under suspicion of having toxic properties, tendencies to cause an allergic reaction (allergenicity).

In other experiences, the substantial equivalence approach is considered to be insufficient, and other systems are created to identify any quantitative or qualitative difference with respect to traditional plants and then submit them to systematic toxin analyses. Other systems argue that it would be convenient to perform tests with all new varieties of plants that are produced, regardless of the production method, and conduct all the necessary tests so as to see their effects, the several environmental factors, their composition through time, etc.

The testing and assessment requirements in Brazil are much closer to this second approach. In that sense, the Annex of the Biosafety Law describes the recommendations to be taken into account when conducting a risk assessment evaluation for both human and animal health, separated into "Organisms consumed as food", where more general analyses as the following are recommended:

- a) Background of use for food of the parental or donor organism in Brazil and in other countries;
- b) Possible effects in the human and animal food chain for the ingestion of the GMO or its derivatives;
- c) Differences of chemical and nutritional composition between the food derived from the vegetal GM and the vegetal non-GM, in nature and after processing.

It is also suggested to analyze more complex matters, such as the similarity analysis of the GMO expression products with known allergens, to describe possible allergic reactions identified after the ingestion of the GMO through evaluation in experimental animals. Further in Annex III there is a description of the elements recommended for risk assessment for animal and human health, especially designed for "Microorganisms used as vaccines".

Food-related suitability assessment of GMO is under the responsibility of the CBS –a division of the Ministry of Health- which main powers are the following: (i) participate and follow-up in both the national and international scopes, the elaboration and reformulation of biosafety provisions; (ii) analyze and study issues related to biosafety, in order to identify its impact and relations with human health; (iii) propose studies in order to aid the Ministry of Health position in the decision making process regarding biosafety issues in health; (iv) aid representatives of the Ministry of Health in Inter-Ministerial Groups related to these matters, also in the CTNBio; (v) promote public debates on biosafety, through open meetings for the community. In Paraguay, risk assessment of food derived from GMO is under the responsibility of the Agricultural and Forestry Biosafety Commission, but decisions on the release thereof correspond to the Ministry of Public Health and Social Welfare through the Feeding and Nutrition National Institute, which shall coordinate the evaluation of the food suitability of GMO within its jurisdiction.

### **3.2.5. Import and export of GMO**

In Argentina, the SENASA manages the regulation and quarantine of plants and animals, as well as compliance with the phytosanitary requirements of the proceedings for the import of plants, parts of plants and animals. In the corresponding form, the importer has to declare whether he is importing genetically modified material. Should it be the case, the import is sent to the CONABIA and the applicant must provide a detailed description of the GMO, the nature of the work and the type of available means he has in order to conduct the research. CONABIA's technical personnel analyzes the safety conditions and formalizes the approval, which is a prior requirement in order to authorize the import. In the meantime, the SENASA temporarily stores the GMO.

In Brazil, Normative Instruction CTNBio No. 2/1996<sup>9</sup> sets forth transitory provisions for the import of GM plants for research purposes. The interested institutions must require authorization to the Department of Defense and Vegetal Inspection (DDIV, according to its Portuguese acronym), of the MAA, which may grant the permit or not, pursuant to the technical opinion issued by the CTNBio. Normative Instruction CTNBio No. 5/1997 sets forth that if the purpose of the vegetal GM submitted before the CTNBio for assessment is research and -according to Normative Instruction No. 2/1996- the subsequent release into the environment, said release shall only be assessed by the CTNBio from the moment the planned release proposal is submitted and provided it obtains a favorable result, the latter pursuant to Normative Instruction No. 3/1996.

In Paraguay, Decree No. 15.290/1992<sup>9</sup> regulates the entrance and circulation of products of vegetal origin under the international transit system throughout the national territory. The Decree requires that any plant lot, its parts, products and subproducts under the international transit system must attach the Phytosanitary Certificate of exportation and re-exportation issued by the competent phytosanitary authority, with its corresponding cargo manifest stating the information on the treatment conditions, points of entrance and exit and circulation paths, terms and place of permanence within the national territory. It does not specifically refer to the biotechnology area.

### **3.2.6. Accumulated regulation experience**

As to the regulations, Argentina is the country with the longest regional experience. Its greatest hits refer to agriculture, accompanying the explosive development of transgenics cultivation, which has turned Argentina into one of the countries with the greatest surface planted with GMO varieties and into the second world exporter of GMO. In Argentina, the commercial release of 12 events has been approved: one of soy, eight of corn, two of cotton and one accumulated event of corn. The main feature introduced in soy is its tolerance to glyphosate; in the case of corn, the events include resistance to insects of the lepidoptera order, to gluphosinate amonium and the combination of both resistances and one event combined by conventional crossing. In the case of cotton, the event incorporates resistance to lepidoptera and to glyphosate.

In Brazil, the CTNBio approved six releases of GMO. In 1998, based on a previous law, it approved *Roundup Ready*® soy, produced by Monsanto. In 2005, in the framework of the Biosafety Law, a cotton crop with Bt. Technology was released. In 2007, the CTNBio

---

<sup>9</sup> President of the Republic of Paraguay: *Decree No. 15.290/1992: It regulates the entrance and circulation of vegetal origin products under the international transit system within the national territory.* Asunción, October 27<sup>th</sup>, 1992.

approved the commercial release of a corn event resistant to insects and to amonium gluphosinate herbicide, and in 2008, an insect-resistant corn event. In the last days, three new GMO have been approved: NK603 corn, RR cotton and GA21 corn, all tolerant to glyphosate and to the vaccine against porcine cicoviruses. There are numerous events under proceedings before the CTNBio.

In Paraguay, the use of an event of GM soy seeds was approved, and there are several commercial products which apply that same event. In the case of cotton, Regulation SENAVE No. 293/2007 sets forth proceedings for the detection, identification and quantification of the supervening presence of GM cotton seeds in conventional seeds. Regulation SENAVE No. 321/2007 exempts producers from responsibility for the possession of GM material provided they comply with the proceedings approved by that same regulation. Those who do not comply with the proceedings shall be punished by the SENAVE. In Uruguay, vegetal GMOs being traded include one of soy (Event GTS 40-3-2) and two of corn (Events MON 810 and BT 11). The country is emerging from a moratorium established in 2007 and it is starting a new transition system which so far has not produced any results in practical terms.

### **3.3. Regulation of intellectual property**

Two systems of protection of intellectual property co-exist in the four countries: the Patent y legislation and the legislation on Plant Varieties, and they are parties to the International Union for the Protection of New Varieties of Plants (UPOV). The concept of patentable "invention" with respect to living matter is similar in the four countries, excluding the patenting of animals and plants and only allowing the patenting of microorganisms and biological proceedings, as long as they are not in the same status as they are in nature. All the countries have the same patentability requirements: novelty, inventive merit and industrial use. The following can be patented: amino acids, peptides, proteins, enzymes, nucleotides (RNA and DNA), plasmids, vectors, monoclonal antibodies, transgenic microorganisms (bacteria, fungi, viruses and ferments), hibridomas, medication, vaccines and cosmetic products.

The countries follow the TRIP (Trade-Related Aspects of Intellectual Property) guidelines, reason for which there are similarities in the treatment of issues such as prior release, inventions developed during the employment relationship, priorities, adequate description, proceedings, terms, examination, the concept of "invention", grace period, contractual and mandatory licenses. The main differences between Argentina and Brazil are those regarding the exploitation by means of licenses, where the local industry is privileged and Brazil allows to patent transgenic seeds. In terms of Varieties of Plants, the four countries have ratified the UPOV Act 78, and they define a Plant Variety in a similar manner, when it is new, distinguishable, homogeneous and stable. The term of protection is longer than 15 years and shorter than 20/30 years. The exception lies in the phyto-improver and the agriculturist rights.

### **3.4. Biotechnology applied to human health**

In the case of Argentina, the approval of drugs developed using biotechnological techniques is under the responsibility of the ANMAT. There is little experience and, although the regulations do not give it a differentiated treatment, there is an interaction on the necessary

requirements between the regulatory entity and the innovator. The proceeding of authorizations to carry out studies of Phase I are negotiated in a constructive dialogue between public and private actors, in which businessmen, researchers and regulators develop experience and build up a basis of knowledge for future regulations. The issue becomes substantially easier when the medication counts with the prior approval of an American regulatory entity or the approval of an important European country. A similar methodology is applied to genic therapies.

In Argentina, research with stem cells since year 2007 has been assigned to the INCUCAI which is in charge of authorizing and monitoring said research with adult stem cells or hematopoietic stem cells in human beings. There are no regulations authorizing research with stem cells originated in human embryos, which is not the case in Brazil. In this country, the issue, although included in the Biosafety Law, is not a CTNBio responsibility. Pursuant to Act 11,105/05 and Decree No. 5.591/05, R&D institutions performing research or therapies using stem cells must submit their projects for the approval of the respective Ethic and Research Committees, and they shall be approved by Decision of the National Health Council. The law authorizes the use of embryos after three years of having been frozen with the consent of the parents, excluding inviable embryos or those with mutations which can entail genetic diseases (COLLI, 2005). Act No. 11,105/05, prohibited human clonation and provides penalties for those who violate it. In May, 2008, by a tight majority of six votes against five, Brazil's Supreme Court authorized the research with embryonic stem cells. This means good news for the discovery of cures for Parkinson or diabetes, among many other diseases, and it positions Brazil at the vanguard in this type of research within the Latin-American scope. In Uruguay, there are rules on human cells and tissues based on the technical requirements of Provision 2004/23/CE as to bioethics and biosafety matters, to which local cultural issues were added in order to grant the protection of human health and prevent commercialization.

### **3.5. Biotechnology and the Environment**

The participation of institutional sectors with the environmental issue has different treatments in the countries and there are generally competition problems and disagreements between the public institutions related to the application productive sectors and the areas created to address environmental issues. In Brazil, this issue has been included in the Biosafety Law. In Uruguay, after a period of inter-institutional conflicts, a consensual solution is near through the issue of a recent decree and the possible future passing of the Biosafety Law.

There are provisions in Argentina supporting the jurisdiction of the institutional sector of the Ministry of Environment as to the regulation of biotechnology. Decree No. 487/2004 sets forth that one of the purposes of the Secretariat of Environment and Sustainable Development (SADS, according to its Spanish acronym) is to "intervene in the development of biotechnology from the point of view of its jurisdiction." This Decree increases one already granted power to the above mentioned Secretariat by means of Provision No. 904/2002 of the Ministry of Social Development and Environment which authorized said Secretariat to interfere in every matter related to modern biotechnology which could have adverse effects on the conservation and sustainable use of the biological diversity. This responsibility does not imply an effective role of the SADS in the decisions, but it implies a participation in the decision making process through the incorporation of a CONABIA representative.

In Paraguay, although there is a complete environmental legislation, the regulatory system of agricultural biosafety depends exclusively on the SENAVE and the participation of the

Environmental Ordering Direction in the Biosafety Commission (CAMBIO, according to its Spanish acronym) created by Decree No. 18481/1997. The new Decree gives participation to the SEMA in the Agricultural and Forestry Biosafety Commission and grants it powers of control over the releases, but it does not define the issue of environmental licensing. It is important to mention that all of the MERCOSUR countries have signed the Cartagena Protocol on Biosafety, but it has only been ratified by Brazil and Paraguay. Argentina and Uruguay have signed too, but they have not ratified it.

### **3.6. Biological diversity and genetic resources**

Argentina has signed and ratified the “Convention on Biological Diversity” (CBD)<sup>10</sup>, which, in Section 19, refers to the handling of biotechnology and the distribution of its benefits, and it sets forth that each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research; however, there is no National Congress provision regulating the access to genetic resources.

The Secretariat of Environment and Sustainable Development, based on Section 41 of the National Constitution<sup>11</sup> and the CBD<sup>12</sup>, passed Regulation 1659/2007<sup>13</sup> whereby the “Guidelines or directives on access to genetic resources and fair and equitable participation of the benefits derived from their use” are approved. This administrative provision, in order to be operational at provincial level, must have express adhesion. Some provinces have passed legislation on the matter.<sup>14</sup> In Argentina there are not consolidated and unified Genes and Germplasm banks at national level. The most complete bank is that generated by the INTA, which coexists with other private banks or national universities and/or research centers.

In Brazil, the Federal Government encourages a bill of Access to Genetic Resources, Traditional Knowledge and Benefit Distribution, which includes a public consultation in order to replace Executive Order 2186-16 of 2001, the purpose of which is to update legislation on research and bioprospection, setting forth mechanisms to distribute benefits with indigenous and traditional communities. Some of the proposed innovations are to provide an embracing and unified treatment to the matter of benefits distribution, stimulating their ethical and sustainable use, defining clear rules and guaranteeing legal safety for the use of genetic resources and their derivatives, as well as the use of traditional knowledge derived thereof, thus reducing the costs of transaction and eliminating bureaucratic obstacles. In Paraguay and Uruguay the legislations are general and there is no specific legislation on these matters.

The four countries urge the enforcement of Section 15 (access and sustainable use of genetic resources and participation in the benefits). As the countries are so dramatically

---

<sup>10</sup>Subscribed in Rio de Janeiro in 1992 and ratified by Law 24375

<sup>11</sup> Section 41 of the National Constitution: “The authorities shall rule on the rational use of natural resources, the conservation of the natural and cultural patrimony and biological diversity.”

<sup>12</sup>Section 15 CBD: “Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses on mutually agreed terms, subject to the prior consent given by the Contracting Party providing the resources.”

<sup>13</sup> SECRETARIAT OF ENVIRONMENT AND SUSTAINABLE DEVELOPMENT. Provision 1659/2007, Buenos Aires, November 1<sup>st</sup>, 2007.

<sup>14</sup> Chubut, La Pampa, La Rioja, Mendoza, Misiones.

different, they urge the need that the patent offices request the origin of the genetic resource and combat biopiracy. There is no agreement in the OMPI in this respect.

### **3.7. Information, participation and labeling**

The issues of information and participation of the public as to commercial utilization of GMO have been addressed differently by the MERCOSUR countries. At this point of the report, we shall try to show the main aspects of the matter, especially regarding the information and participation of the public in the decisions, information for consumers and labeling or identification of seeds and foods derived from GMO.

In Argentina and Brazil there are no mechanisms which allow the participation of the public in the process of authorizing products or processes based on GMO. In Argentina, citizens participation in the decisions regarding GMO is considered a pending issue included in the Strategic Plan of Development of Agricultural Biotechnology and present in several bills which have not yet been passed. The approaches consist mostly in consultations which are not binding for the authorities, but it is mandatory that they publish the results and publicly justify contrary decisions.

In the case of Paraguay, the public in general shall have access to information on field tests and other proposed uses of the authorized events, except for information considered confidential. The Agricultural and Forestry Biosafety Commission is authorized to provide information related to the Center of Information Exchange administered by the SEAM, of the Cartagena Protocol. Technical Secretariats of the Commission shall be in charge of systematizing information related to the different uses proposed such as experimenting, field testing, issued decisions, authorizations granted by the MAG -among other proceedings-, which shall be available once the Commission has pronounced its decision.

In the case of Uruguay, the legislation sets forth non-binding consultation mechanisms. Prior to the submission before the GNBio for the decision making on an application, information shall be provided and suggestions received on the results through express opinions, public hearings and other mechanisms, in a process which has not yet been defined, the regulation of which corresponds to the Risk Management Commission.

In terms of releasing information for the public, Brazil sets forth that extracts of the opinions and technical decisions rendered by the CTNBio must be published in the Official Gazette, and that the justified vote of each member thereof must be stated in the Biotechnology Information System. In Uruguay the new regulations provide that the submission of applications for authorization of new GMO events shall be disclosed to the public through information channels. Also, a system to receive complaints for the non-fulfillment of already granted authorizations shall be created through the Technical Secretariat of the CGR. In Argentina, SAGPyA's decisions are published in the Official Gazette, and in Paraguay, Decree No. 12706 states that the public in general shall have access to information on field tests and other proposed uses of the authorized events, except for the case of information considered confidential. In Uruguay, Decree No. 468/2008 sets forth responsibilities regarding the release of information for the public.

Commercial labeling of foods derived from GMO has not been widely divulged in the MERCOSUR countries. Argentina has a broad experience in the labeling of seeds. However, there are no national regulations for the labeling of foods derived from GMO. Some provinces and districts have passed regulations on the labeling of GM food and there are

some bills awaiting to be passed. For the national authorities, the legal force of those regulations is irrational, impracticable and contrary to the National Constitution. Foods and ingredients produced from animals fed with a ration containing transgenic ingredients also have to be labeled. Foods and ingredients which do not contain nor are produced from GMO may or may not include a label stating "transgenic-free" in case there are similar transgenics in the Brazilian market. There is a specific symbol for this identification.

In Paraguay, Law No. 1334/1998 of Consumer and User Defense includes the responsibility of suppliers to provide clear information on the composition, quality and price of the different products and services in defense of the economic integrity of the consumer and on the risks said products and services may present, but there are no specific regulations for GMO. In Uruguay the Biosafety National Cabinet (GNBIO, recently created by Decree No. 468/2008), shall promote actions tending to implement the voluntary labeling as "GM" or "non GM", applicable to food in which it is possible to evidence, through the analysis of the final product, the presence of DNA or GM proteins.

### **3.8. Policies to promote biotechnology**

In Argentina, the Development and Production of Modern Biotechnology Act sets forth provisions to promote the development and production of Modern Biotechnology for a term of 15 years. The beneficiaries must submit research and development projects based on the application of modern biotechnology or projects of application or execution of modern biotechnology aimed to the production of goods and/or services or to the improvement of processes and/or products. The projects shall receive different types of fiscal benefits.

Projects shall have an evident technological impact and shall be directed by professionals with technical expertise and economic and/or financial capacity to execute them and who fulfill the biosafety requirements set forth by the regulations in force. They shall further have an innovative content with industrial application and imply economic and social impact, reduction of production costs, increase of productivity or other effects considered proper by the Application Authority. Priority shall be given to projects which respond to the priorities set by the national or provincial governments, which have direct relation with the promotion and development of micro and small companies of technological base, to projects which generate an increase in the use of human resources; which have a social and economic local and regional impact and generate an increase of the competitiveness of products and services. The Law creates the Fund for the Encouragement of New Projects in Modern Biotechnology, which finances initial capital contributions for new entrepreneurs, formed by the resources which are annually allocated through the General Budget Law of the National Public Administration and other income. Beneficiaries agree to request patents before the Industrial Property National Institute.

The Consulting Commission for the Promotion of Modern Biotechnology shall act as advisory organization of the Application Authority. It shall be formed by representatives of institutions of the private sector and/or the different activities involved in the biotechnological development, trade and foreign affairs.

The "Bicentenario" (2006-2010) National Strategic Plan of Science, Technology and Innovation, the Transversal Integrating Program of the National Innovation System (PROTIS, according to its Spanish acronym) of the present Ministry of Science and Technology and the Strategic Plan 2005-2015 for the Development of Agricultural Biotechnology are examples of

the interest shown by the national State to plan biotechnological development, although to date there is no certainty as to their results and/or the continuity of their application.

In Brazil, Law No. 10332 creates a financing mechanism for the Program of Science and Technology for Agricultural Business, the Program to Promote Health Research, for the Biotechnology and Genetic Resources Program–Genoma and for the Innovation Program for Competitiveness. Law No. 10973 encourages innovation and scientific and technological research in the production area.

Decree No. 6041 of February 8<sup>th</sup>, 2007, institutes the Biotechnology Development Policy and creates the National Biotechnology Committee. The policy purpose is to set a proper environment for the development of innovative biotechnological products and processes, to encourage a higher efficiency of the productive structure, the increase of the innovation capacity of companies, the incorporation of technologies, the generation of business and the expansion of the country exports.

Decree No. 6041 creates sectorial areas which shall be the target of specific programs: Human, Agricultural, Industrial and Environmental Health. For each sectorial area, strategic sectors shall be defined, as well as priority areas and areas of the biotechnology borderline. The actions to structure the Biotechnology Development Policy shall also be oriented to specific programs in order to provide financing –also non-reimbursable financing as the strengthening of the venture capital contribution-, for the creation of companies or networks of innovating companies of biotechnological basis and fiscal instruments. It also includes support for the creation of human resources, infrastructure and the creation of a regulatory framework for industrial biotechnology, in terms of innovation and industrial property, bioethics, biosafety, access to genetic resources, etc. Supports are channeled through the Biotechnology Sectorial Fund.

The Law creates the National Biotechnology Committee (CNB, according to its Portuguese acronym) in order to coordinate and implement this policy. Said Committee shall be formed by representatives of Ministries, Agencies and Public Institutes related to the biotechnological R&D area. The CNB shall be guided by the Competitiveness Biotechnology Forum and by collective bodies of the federal government, including CTNBio, CONABIO, CGEN, CNS and CONSEA. Participation of the different sectors of civil society is guaranteed through the composition of the Competitiveness Biotechnology Forum.

In Paraguay, Law No. 1028/1997 of Science and Technology institutes the national system of science and technology, formed by the aggregate of bodies, national public and private institutions, natural and artificial persons dedicated or related to scientific and technological activities. Said institutions stimulate and promote scientific and technological research, the generation, release and transfer of knowledge; invention, innovation, scientific and technological education; metrology services, normalization and quality assurance, the development of regional technologies and management of science and technology.

The scientific and technological development of the country shall be guided by specific policies and programs impelled by the public sector, duly coordinated and in relation with the private sector. Long-term policies shall contain the guidelines and general strategies for the scientific and technological development of the country. Mid-term policies shall be based on the latter and in the priority needs of national development, and shall have a five-year projection. Science and technology policies shall be developed by means of intersectoral, interdisciplinary and interinstitutional programs.

The direction, coordination and evaluation of the national system of science and technology shall be under the responsibility of the National Council of Science and Technology

(CONACYT, according to its Spanish acronym), which is instituted by this Law as a public autarky of mixed composition, under the aegis of the Presidency of the Republic.

In Uruguay, a process of development of science and technology started in 1985, and it involved a series of institutional and governmental policies. The Innovation Ministerial Cabinet (GMI, according to its Spanish acronym) was created on April 14<sup>th</sup>, 2005, a coordination instance of the highest level of the Executive Power, formed by the Ministers of the productive and economic areas (MEF, OPP, MIEM and MGAP) and coordinated by the MEC. The purpose of this structure is to coordinate and articulate governmental actions related to the Innovation, Science and Technology activities for development. In 2005, the GMI elaborated the bases of a National Strategic Plan of Innovation, Science and Technology Policies for Development, which implies the elaboration of a Strategic National Plan, defining goals, purposes and priorities, and paying special attention to certain areas and sectors, specifically mentioning biotechnology.

The National Agency of Research and Innovation (ANII, according to its Spanish acronym) was created in 2006. The main goals of the Agency included the design, organization and administration of plans, programs and instruments oriented to the scientific and technological development and the deployment and strengthening of the innovation capacities. Another strategic goal was the promotion of the articulation and coordination among the different actors involved in the creation and use of knowledge so as to strengthen synergies among them and take as much advantage as possible of the available resources. Consequently, the creation of the GMI and the ANII arises as promising, as they are scopes to develop a plan of action which tends to revert the lack of a Biotechnology National Program.

The Tax Amendment Law No. 18083 of December 27<sup>th</sup>, 2006 sets forth a new taxation system which is in force at present in the country. Decree No. 208/007 specifically sets forth different Regulatory Provisions of the above mentioned Law. That is how the Ministry of Economy and Finance, on June 18<sup>th</sup>, 2007, stipulated –by means of said Decree No. 208/007- that the biotechnology area is exempted from the income derived from research and technology, this being the regulation in force.

## 4. Institutional Framework in the MERCOSUR

As to the political framework in which this study is conducted, it is worth mentioning the possibility that the results contribute with supplies to the negotiation process initiated by the political structure of the MERCOSUR. The Southern Common Market has created an Ad-Hoc Group on Agricultural Biotechnology (GAHBA, according to its Spanish acronym), through Resolution No. 13/04 (MERCOSUR/GMC/RES. N°13/04), and sets forth the Negotiation Guidelines for the GHABA through Resolution No. 13/05 (MERCOSUR/GMC/RES. N°13/05). In accordance with these instruments, the negotiation includes the following actions:

- ⇒ Harmonize and coordinate the Regulatory Frameworks on biosafety and the related regulations between the MERCOSUR States Parties.
- ⇒ Start the analysis on the coordination of the commercial releases of GMO.
- ⇒ Analyze the consequences of labeling food derived from agricultural biotechnology in both the regional and the international scopes.

As every Ad-Hoc group created by the MERCOSUR, the GAHBA has a fixed term to fulfill its purposes, and it expects to finish its work by the end of 2008. The most remarkable progress can be seen in the following aspects:

- a) As to the evaluation and elaboration of alternatives to harmonize and coordinate regulatory frameworks on biosafety and the related regulations among the countries, the Group reaffirms that the harmonization and coordination proposals should focus in the study of options aiming to the regional adoption of internationally accepted principles (especially the criteria and proceedings on risk assessment), leaving the resolution of aspects such as the decision making structure or specific implementation issues to the national discretion.
- b) There are deep differences as to time for the processing of the different authorization requests and the corresponding authorizations; differences in the amount and type of authorized events for research among the States Parties and on the possible consequences derived from the lack of coordination for commercial releases. Said differences could entail problems such as the following:
  - ⇒ Restrictions in commerce due to the asymmetries for the authorization of GMO between exporting and importing countries in the region;
  - ⇒ Possibility of supervening presence of unauthorized GMO in the importing country;
  - ⇒ Risks of introduction of unauthorized GMO by means of informal entrance, especially in borderline areas;
  - ⇒ Decrease of alternatives for the provision of basic raw materials, in products such as corn.
- c) Possibility of making a distinction of the following types of commercial approval pursuant to the intended use or purpose of the GMO in issue:
  - ⇒ Commercial cultivation;
  - ⇒ Human feeding;
  - ⇒ Animal feeding;
  - ⇒ Manufacturing or processing.

With respect to the possible alternatives to mitigate the effects derived from the lack of coordination, the Group remembered that Argentina proposed to work based on the approach of the "proposed use" and that Paraguay argued that it was a matter of Agricultural Policy in general, proposing the discussion of a "Strategic Plan". Uruguay proposed to move forward through the instrumentation of formal mechanisms of exchange of information, interaction and mutual cooperation among the competent authorities. The Group is elaborating a Technical Report for the Common Southern Market with conceptual issues, definitions, international aspects, situation of the MERCOSUR and evaluation of the cost of labeling foods derived from modern biotechnology.

## **5. Conclusions and recommendations**

The development of the provisions for the regulation of agricultural biosafety does not have a bylaw for the MERCOSUR. The countries started to create a working instance for the MERCOSUR, aimed to identify areas of agreements and disagreements, and to perform an analysis of opportunity, possibility and characteristics of the regional homogenization processes, after a long period of postponement while they expected decisions within the context of the discussions on the Codex Alimentarius.

In the MERCOSUR countries, the situations are also differentiated, according to their domestic specificities. In terms of regulations, Brazil has the advantage, as it has a centralized system created by the Biosafety Law, and an instance of binding technical multisectorial evaluation as to risk assessment, performed by the CTNBio. In Argentina the system was organized within the context of the SAGPyA, with the participation of non-binding consulting instances of other State areas related to the matter. In Paraguay, the regulatory system is centralized in the SENAVE, with the advisory participation of other areas of the State, also non-binding. Uruguay is undergoing a transition process, and it moves forward to a centralized system in a National Cabinet unit with a centralized evaluation process. At present, even though the administrative proceedings and the decision making process for GMO approvals for agricultural use are different in the four countries, the main scientific and technical criteria for GMO risk assessment in the four countries are similar and in general they coincide with international regulations in that respect, assuring a common basis for their biosafe use.

As to intellectual property, both in patent regulations and in producer rights there is great similarity. As to patents, there is a coincidence in the way in which national legislations have accepted the TRIP statements, especially as regards "living matter" as a patentable invention; with respect to the protection of plants varieties, the four countries have accepted the UPOV Act 1978, which in practice implies a harmonized regulatory framework. With respect to the protection and exploitation of biological diversity and the applications of biotechnology, the four countries have ratified the Convention on Biological Diversity. However, the application of some of its principles is still pending, especially as to the identification of the origin of genetic resources and the exercise of sovereign rights in the participation of the economic benefits said resources generate from their application by the industry.

### **5.1. Situation and experience of each country**

The issues addressed in this study are broad and they include the most relevant effects of the regulatory problem of the countries, reason for which it contributes with extensive information on the status of the situation of biotechnology regulation in the MERCOSUR, the main differences and similarities as a basis for a comparison with the regulation of the European Union and the design of a cooperation framework. The study includes aspects out of which it is possible to make contributions for the treatment of the present problems of the MERCOSUR countries. This “reduced” agenda includes the main concerns of the region experts, the main demands which rise from the social and economic processes and the priorities fixed by the governments of the four countries for the MERCOSUR organization. In this context, the European Union experience and what can be understood from it by making a comparative analysis is significant in two dimensions:

- a) The contribution in order that each State Party perfects its domestic regulatory process, improving the domestic proceedings and increasing the scientific capacities for regulatory purposes.
- b) Criteria, approaches and experiences in the harmonization of the national rules and regulations which contribute to the construction of a regulatory framework for the MERCOSUR.

Finally, it is important to mention that the study has identified the importance of including some emerging issues, such as the actions taken to improve the public perception of biotechnology, the stimuli for accelerating the State intervention in the regulation of the areas not covered by the present provisions, and the stimuli for the issue of regulations that favor innovation and competitiveness of the companies. Consequently, the present situation requires regional consensus mechanisms with respect to regulatory and technological aspects, so as not to deepen the relative delay of the MERCOSUR with respect to developed countries.

## **5.2. Priorities arising in the MERCOSUR**

The present decision making process on biotechnology is subject to regulations and institutions set forth by the authorities of each country, which present very different situations. In that sense, the countries of the region present differences in their biological diversity, in the use of their soil, in their participation as exporters of agricultural products, in the infrastructure they have, in the regulatory institutions and in the role they give to biotechnology for their future development.

### **5.2.1. Priorities in the application of biotechnology**

Among the different sectors in which biotechnology has developed at regional level, its application has acquired its greatest relevance in the agricultural production, a very important sector in the economy of the MERCOSUR States Parties. This situation has generated discussions regarding agricultural and food-related biotechnology, with a significant environmental and social impact, which has generated fear in the countries regarding the appearance of commercial tariff barriers. Harmonization of the regulations which govern GMO and the foods derived therefrom is a desirable purpose. Yet, it is not an easy purpose due to the different regulations to which GMO are submitted in the different countries. In the field of innocuousness assessment of the food derived from GMO, for instance, there are

remarkable differences among the countries, as they have different conceptual approaches discussed in an international debate which has been going on for years. Harmonization would be ideal for maximizing the use of financial, institutional, technical and human resources. At technical level, harmonization involves agreements on methodologies, information requirements, evaluation standards and criteria to ascertain unacceptable risks. However, at conceptual level, the situation involves general agreements which today are far from being attained. A starting point for this effort could be an acknowledgement of the economic benefits and other types of benefits that could appear from yielding the benefits of agricultural biotechnology in the MERCOSUR.

### **5.2.2. Priorities in the organization of the MERCOSUR**

As to the political framework in which this study is conducted, it is worth mentioning the possibility that the results contribute with supplies for the negotiation process within the MERCOSUR context. The Common Southern Market has created an Ad-Hoc Group on Agricultural Biotechnology (GAHBA, according to its Spanish acronym), through Resolution No. 13/04 (MERCOSUR/GMC/RES. N°13/04), and set forth the Negotiation Guidelines for the GHABA through Resolution No. 13/05<sup>15</sup>. In accordance with these instruments, the negotiation includes the harmonization and coordination of the regulatory frameworks on biosafety, the coordination of the commercial approval of GMO and the analysis of the consequences of labeling.

### **5.3. Importance of the EU contribution**

The comparative analysis between the MERCOSUR policies and regulations and those of the European Union has many difficulties, as the common regulations among the MERCOSUR countries in the biotechnology area is quite scarce, thus turning the comparison between both systems irrelevant. In this context, the chosen alternative is to conduct a comparative analysis of the regulations within the MERCOSUR, choosing the most critical points, and then compare them with the EU regulations, trying to find concepts, experiences, strong and weak aspects of the legal structure of each country and the overcoming perspectives.

The ascertainment of the critical aspects aims to identify barriers and contribute with knowledge and information for the following purposes:

- i. Progress in the development of a regulatory framework in the MERCOSUR countries which allows to include biotechnology as a key factor for economic and social innovation and development.
- ii. Harmonize the countries capacities so as to be able to develop a regulatory framework of biotechnology within the MERCOSUR.

These critical aspects should address the problems of the most dynamic economic and social sectors of the region and contribute to the political organization of the MERCOSUR.

---

<sup>15</sup> (MERCOSUR/GMC/RES. N°13/05)

**Annex I**  
**Report on Argentina**

# 1. Introduction

Biotechnology development in Argentina dates from the beginning of the 1980's, when local companies started to develop biotechnological products and processes. Their activities later on would generate the creation of an incipient industry. Public institutions of the science and technology area followed-up this process and, in 1982, a Biotechnology National Program was launched. Gradually, cooperation agreements were also entered into with Brazil -among them, the Argentina-Brazil Biotechnology Center (CABBIO, according to its Spanish acronym) – France and other countries of the European Economic Community. This favorable environment lasted until the mid-nineties, time during which the activity decayed due to the crisis and the opening of the economy, and due to changes in the companies strategies. However, in the last years, it is possible to observe a new boom of this area in the country, with interesting developments on the part of some companies and with a State action on the matter which seeks to accompany and frame said processes.

At present, the biotechnology area in Argentina is formed by approximately eighty companies dedicated to the development of products and processes. They mainly constitute a group of private companies which operate in the production of seeds and vegetal micropropagation, animal reproduction, cultivation and production of vaccines, medications, inoculants and enzymes. Approximately 80% of this companies have national capital. Small and medium-size companies prevail strongly, and their activities are almost exclusively biotechnological. There is also a small number of bigger companies which further control other activities related to biotechnology, such as the production of seeds, drugs and food. As a whole, the majority of the local activities takes place from the adaptation and small improvements of radical changes carried out by a small number of big companies with headquarters abroad. All of these companies invoice more than 950 million pesos per year, they export 52 million dollars, they import less than 20 million dollars and hire about 5,000 people. Their annual expense in innovation is of approximately 5% of their sales and approximately 10% of their staff is dedicated to R&D. Almost all of these companies have active relations -formal and informal- with R&D groups and with researchers settled in public institutes and centers. Business networks for the execution of joint projects, on the other hand, present a less advanced development.

The industrial application of biotechnology has had its greatest local impact in the pharmaceutical industry, where a long biomedical tradition is combined with an active national industry, which dominates almost 50% of the market. The presence of the companies and their biotechnological products in the pharmaceutical industry is quite strong. There is a significant number of products based on their own developments and several are produced and commercialized under license. In a similar area, it is important to mention the development of transgenic cows, the milk of which can be used to produce medicine such as human insulin and human growth hormones. The most important project in this area was developed by Biosidus, a national capital company, in cooperation with researchers of the science and technology system (mainly from the UBA –University of Buenos Aires).

From the livestock-related point of view, the production of veterinary vaccines constitutes a relevant sector, with the application of DNA technologies for the production of antigens. The production of a vaccine against foot-and-mouth disease of high power and security by means of biotechnology during the sanitary emergency of 2000-2001 showed the reaction capacity of the veterinary industry, with high quality and biosafety standards at international level. The biotechnological activity in the food-related industry is diversified, with emphasis in the industrial fermentation division, including probiotic additives to improve human intestinal flora in yogurt, milk and cheese.

With respect to crops, the first biotechnological product used in the country was the glyphosate-resistant soybean, known as “RR” (Roundup Ready), which had a great deal of adoption and acceptance in its different varieties. In the last years, different transgenic crops varieties have been incorporated to the agricultural strategies. The greatest innovation effort was with corn, regarding to which nine transformation events have been released. The list of released crops includes soy, corn and cotton. Thanks to these developments, in 2007, Argentina was the second world producer of genetically modified crop, with 19.1 million hectares (17% of the crop global surface). Genetically modified soy, corn and cotton have yielded earnings of more than 20,000 million dollars in the last ten years. To sum up, Argentina has a quite important business basis regarding economic, technological and productive factors, with experience and dedication in the use of processes and the elaboration of biotechnological products, which constitutes a reasonable platform for future development in this field.

## **2. Regulation and institutions**

In general, the legislative regulation framework of biotechnology is given by the National Constitution, which in Sections 41 and 42 sets forth environmental and health protection rights for all the inhabitants. Specific regulations in several areas, however, are set forth in different provisions and their fulfillment is under the responsibility of public centralized and decentralized departments of the State. In the agricultural area, the main authority is the Secretariat of Agriculture, Livestock Breeding, Fishery and Food (SAGPyA, according to its Spanish acronym), of the Ministry of Economy and Production. The SAGPyA is responsible for elaborating and executing plans and programs as well as production, marketing, technology and sanitary policies in agricultural, fishing, forestal and industrial aspects. The main bodies of agricultural biotechnology regulation depend on the SAGPyA: the Seed National Institute (INASE, according to its Spanish acronym), the National Service of Sanitation and Food-related Quality (SENASA, according to its Spanish acronym), the National Commission of Agricultural Biotechnology (CONABIA, according to its Spanish acronym) and the Direction of Agro-Food Markets (DIMEAGRO, according to its Spanish acronym). On the other hand, regulations in the human health area are under the responsibility of the Ministry of Health, which jurisdiction in biotechnology issues is exercised through the Drug, Food and Medical Technology National Administration (ANMAT, according to its Spanish acronym), which operates through the Food National Institute (INAL, according to its Spanish acronym) and the Medication National Institute (INAME, according to its Spanish acronym).

As to the environmental aspects, in 1984 Argentina approved the Convention on Biological Diversity (CBD) and appointed the Secretariat of Environment and Sustainable Development as the application authority. The competent authority on this matter is the National Advisory Commission for the Conservation and Sustainable Utilization of Biological Diversity (CONADIBIA, according to its Spanish acronym), under the aegis of the Secretariat of Environment. In this context Argentina has also signed the Cartagena Protocol, a United Nations agreement which purpose is to set forth common rules for movements of GMO across borderlines in order to guarantee the protection of biodiversity and human health at worldwide level. Furthermore, the purpose of this protocol is to contribute to guarantee an adequate level of protection in the transfer, manipulation and safe use of live organisms modified as a result of the application of modern technology. As to the food scope, the

National System of Food Control is in force in the country, which main purpose is to harmonize legislation on the matter: the Argentine Food Code, the ANMAT organizational structure, the rules and regulations and the structure of the SENASA and the MERCOSUR provisions on the subject. The SENASA has jurisdiction to formulate rules and regulations for entities which produce and elaborate organic food of animal origin. The above mentioned INAL, on the other hand, is responsible for controlling the so called “conditioned food” and for the fulfillment of the Argentinean Food Code, surveilling the innocuousness and quality of the products under its jurisdiction.

## 2.1. Agricultural biotechnology

The approach that Argentina applies for the regulation of biotechnology departs from the general hypothesis that regulations must use criteria and proceedings which do not hamper the development of technological innovations. In this context, it is argued that security is achieved through the definition, assessment and management of the risks associated to innovation. In terms of biosafety, protection with respect to known or identified risks derived from the application of technology is considered in particular, pursuant to the present status of available knowledge.

The Argentine rules and regulations define a GMO as:

- ⇒ an organism (vegetal, animal, microorganism or virus),
- ⇒ into which precise and defined genetic information has been introduced,
- ⇒ deliberately and aimed to obtain a certain phenotype,
- ⇒ the introduction is made in such a way that genetic information could not have been acquired by that organism by means of mutations, recombinations or other forms of genetic transfer recognized as mechanisms which operate in nature without human intervention.

Risk assessment focuses in the following aspects:

- a) identification of all the organisms involved (donors, receptors, etc.),
- b) characterization of the organisms involved in the process of obtaining the GMO (such as familiarity or pathogenicity),
- c) definition of the manner in which the GMO shall be used (scale, containment),
- d) characterization of the areas and of the other organisms which constitute the context in which the GMO is inserted.

The Argentine regulatory framework considers each product or release individually. This means that even though the existing precedents are taken into account and similar cases are considered as valid information for the assessment, the data is not transferable among cases and each case and each applicant must be consistent and self-sufficient as to the provided information. The regulation at present in force includes directives on tests and releases into the environment, as well as the guidelines to authorize the marketing or production of food derived from GMO, of both vegetal and animal origin. Pursuant to a SAGPyA provision, assessments in this area are conducted in two phases: the first one is related to experimental releases aimed to define the possibility of effects on the environment, and the second is related to assessments of extensive releases, the purpose of which is to ascertain whether the releases of the GMO generate an impact in the environment which significantly differs from that which would be produced by the non-GM homologous organism. On the other hand, the approval for the use of a GMO as food raw material depends on information

of two types: that requested to the applicants, which is specific for their needs (food-related suitability, structure of our exportation market, etc.); and that provided by the CONABIA on the behavior of the GMO in issue throughout the tests which have been conducted. The CONABIA assesses that the GMO crop does not cause risks to human health, the agro-ecosystem and the flora and fauna related thereto, and the granting of a commercial authorization depends on the statement that the GMO is as safe as its non-modified counterpart.

## **2.2. Regulations in the human health area**

The regulation in force does not provide a differentiated treatment to medication developed through biotechnological techniques. The proceedings of authorizations to conduct studies on the tolerance of a drug is negotiated among the regulation instances, the companies and the researchers. However, the process is remarkably easier when a medication has been already approved by a regulatory entity of the United States or some developed European country.

In this area, it is interesting to mention the case of biotechnological medication produced by BIOSIDUS. This company has registered medication such as insulin and the growth hormone, produced by a proceeding which uses live animals. The trials with animals were executed under the supervision of the CONABIA and the SENASA, while the approval of the drug is processed before the ANMAT. As a result of experiences like these, the ANMAT created a Genic Therapy Commission and requested further information, thus beginning a joint learning process between this body and the companies. Research in regenerative medicine and the use of stem cells, on the other hand, was not contemplated in the legal provisions until 2007, and that caused that no institution included the monitoring thereof under its jurisdiction. However, in that year, the Ministry of Health set forth the enforcement of two relevant regulations: on the one hand, it decided that the National Central Coordination Institute for Organ Implant and Ablation (INCUCAI, according to its Spanish acronym) would have jurisdiction on the activities related with the use of cells of human origin for their subsequent implant in human beings; on the other hand, it created the Commission of Clinical Research Applied to Human Beings, within the scope of the Ministry of Health, which, among other things, must propose the regulatory framework for the research lines related with scientific and technological progress.

The National Agency for Scientific and Technological Promotion, which is subordinated to the Ministry of Science and Technology, has, since 2006, a multidisciplinary commission which advises in cases in which requests for the financing of research using stem cells are submitted. Since 2008, this commission also interacts with the INCUCAI and the Ministry of Health and is in charge of releasing information on the matter. With respect to medication, there is the so called "Farmacopea Argentina" (Argentine Pharmacopoeia), an official code where types of drugs and medication necessary or useful for exercising medicine and pharmacy are published and described. Its organizational structure, governed by the ANMAT, has a deputy biotechnology technical commission which advises on the inclusion in the pharmacopoeia of biotechnological products which are already in the market. Within the scope of the ANMAT, there is a National Commission of Biotechnology and Health (CONBYSA, according to its Spanish acronym), formed by representatives of said agency and of the Biotechnology Argentine Forum. The purpose of the CONBYSA is to analyze the rules and regulations in force which govern the development, elaboration and approval of biotechnological products aimed for health and human consumption.

## **2.3. Regulations in the environmental area**

The purposes of the Secretariat of Environment and Sustainable Development (SAyDS, according to its Spanish acronym), subordinated to the Chief Cabinet of Ministers are, among others, to intervene –from the point of view of its jurisdiction- in the development of biotechnology. That implies that it can act regarding the transfer, manipulation and use of GMO which may have effects in the conservation and sustainable use of biological diversity. Within the scope of the SAyDS, the National Advisory Commission for the Conservation and Sustainable Use of the Biological Diversity (CONADIBIO, according to its Spanish acronym) has a deputy technical commission on genetic resources and biotechnology, which responsibility is to make recommendations on issues related to the use and access to genetic resources and the technologies related thereto. This commission is further responsible for making recommendations regarding the practical application of technologies that use biological systems and live organisms or their derivatives to create or modify products or processes for specific uses. Furthermore, the country has a National Strategy on Biological Diversity, elaborated by the SAyDS in cooperation with the National Institute of Agricultural Technology (INTA, according to its Spanish acronym), the National Parks Administration (APN, according to its Spanish acronym) and the Argentine Committee of Institutions which subscribed the International Union for Conservation of Nature (IUCN). The strategy contemplates the promotion of equitable participation in the benefits derived from the proper use of genetic resources. However, access to and conservation of said resources so far have not been regulated by law.

## **2.4. Biosafety of foods derived from GMO**

The approach adopted in Argentina is based on the comparison of the new food with that traditionally used and considered safe. The most widely known modified crops in the country are soybean and corn, with their respective derivatives. Food products elaborated with GMO derivatives include cookies, sauces, soy beverages, chocolates, pâté and cereal bars, among others. Risk assessment of said food corresponds to the SENASA, through its Advisory Technical Commission on the Use of Genetically Modified Organisms, which analyzes the different aspects in which new food can be different from traditional food. The criteria applied is based on documents of the FAO and in regulations from Australia, Canada, the European Union, Japan and the United States, regarding the requirements and criteria on biosafety of food or the ingredients derived from GMO and their suitability for human and animal consumption. Risk assessment includes an evaluation of the innocuousness, the purpose of which is to define whether there is any nutritional danger or dangers of any other kind and, should that be the case, gather information on their characteristics and gravity. Furthermore, regulation contemplates surveillance after placement in the market. The SENASA is also the regulatory entity of the international trade of food derived from GMO. On the other hand, regulation of the innocuousness of food for human health is under INAL's scope of responsibility, which is subordinated to the ANMAT. The INAL has its own laboratories and keeps a communication network with its departments in the provinces, as well as with provincial and municipal divisions in charge of monitoring food.

## 2.5. Public information and participation

Argentina has great experience in seed labeling, but little experience in tagging food derived from GMO. In fact, for more than seventy years there has been a certification system for grain deposited in silos and elevators; there is also a typification nomenclature and identity certifying entities. The SAGPyA has stated that containers of vegetal genetically modified organisms must be labeled, while the INASE has set forth the requirements for the labels of hybrid and transgenic seeds.

With respect to food, there are no specific criteria for labeling food related to GMO. However, the SAGPyA created the Argentine System of Traceability for the Agro-Food Sector (SAT, according to its Spanish acronym) in 2002. The purpose of this system is to identify the origin or sanitary status of a product or national agricultural production and approve the food resulting therefrom. The SENASA, on the other hand, created the Federal System of Control for Agrochemical and Biological Products, which provides the traceability of phytosanitary products. Additionally, some provinces and municipalities have passed regulations on the labeling of food derived from GMO, generally invoking the right to consumer information, although it has been criticized that the legal effect of many of these rules is unreasonable, impracticable and contrary to the National Constitution and several federal laws.

The National Constitution provides the general framework of rights in this area: on the one hand, it sets forth the right to environmental protection, and on the other, it gives consumers and users the right of protection of their health and the right to proper and truthful information. On the other hand, the law which sets forth the right to information provides the free access to public environmental information. Consumer defense law provides for the labeling of food that the supplier is forced to provide: said labeling has to be true, clear and detailed regarding the essential characteristics of the provided goods and services. However, some have argued that the inclusion of GMO within the scope of these regulations does not contribute to the enforcement of the consumers rights and that, on the contrary, that could lead to confusion and disinformation. From this point of view, information on whether food is transgenic or not or on whether it contains ingredients which may come from GMO is impossible to obtain and state, thus resulting inefficient and irrelevant, reason for which it does not contribute to the right of information. The official position of the Argentine government, submitted before the Labeling Committee of the Codex Alimentarius -main international scenario for the debate of this matter-, is that labeling of food derived from GMO corresponds only whenever there is a change in the quality or nutritional content, or whenever unexpected allergenic qualities are introduced, that is to say, whenever there is an objective and measurable modification with respect to its conventional homologous product.

With respect to citizens participation in decisions regarding GMO, that is a pending subject of Argentina's regulatory systems. There is a law which sets forth the national environmental policy and the protection of biological diversity and further explains the right of citizens to be consulted regarding the environment preservation. Nevertheless, the official position is that the present rules and regulations on administrative proceedings include criteria of confidential information which prevent the release to the public; provisions of public organs, on the other hand, do not include any regulations on the matter. The issue has been addressed by the authorities responsible for the regulation of agricultural biosafety and is part of the objectives which have not been reached in the implementation of the respective strategy. Furthermore, the matter was addressed in one of the sections of a bill on biotechnology and agricultural biosafety which was not passed by the National Congress. The proposal considered the inclusion of consultations in which the opinion or the objection of participants would not be binding for the calling authorities, but it would be mandatory to

publish the results. Citizenship participation was also considered for the assessment of the environmental aspect.

## **2.6. Intellectual property rights**

Section 17 of the National Constitution sets forth the general framework of legal protection of innovations, as it states that “any inventor shall be the exclusive owner of his invention for the term granted by the law”. With respect to the protection of intellectual property of biotechnological inventions, there are two main laws: on the one hand, the law of patents and utility models, and on the other, the law of seeds and plant varieties.

The first of these acts derives from Argentina’s adhesion to the Trade-Related Aspects of Intellectual Property Rights (TRIP), consented by the World Trade Organization, and its application authority is the Intellectual Property National Institute (INPI, according to its Spanish acronym). The law admits the patenting of new artificially obtained microorganisms by means of genetic engineering, that is, they must fulfill the requirements of novelty, inventive merit and industrial use, provided they are modified and different from those existing in nature. At the request of the SAGPyA, the INPI issued supplementary directives on patenting in this area, by means of which the national guidelines as to the protection of biotechnological inventions are set forth, the different technical aspects of intellectual property are regulated and their legal construction is defined. The INPI does not have any regulations which require the applicant of a patent to evidence the origin of the genetic resource which is part of the purpose of an invention patent.

The law mentioned in the second place, regarding vegetal innovations, was elaborated in order to guarantee agricultural producers the identity and quality of the seed they use and to promote the means for the creation, multiplication and marketing of seeds. The application authority is the INASE. This law gave rise to the creation of the Cultivar National Registry, which authorizes the marketing of plant varieties in the country, and the Cultivar Property National Registry, oriented to protect the property right of the producers of new plant varieties as a recognition for their phyto-improvement activity. In order to register transgenic varieties it is not required to evidence the right of legitimate use of the genetic feature, which could originate problems in the future in case two owners claim the same feature or the same gene and there would be no way of knowing who is the owner through patents, contractual licenses or other means of evidence. Foreign applicants must file their requests through a representative with legal domicile in Argentina.

**Annex II**  
**Report on Brazil**

# 1. Introduction

Important sectors of the Brazilian economy are users of biotechnologies, although the institutional environment and the economic scenario have sometimes hampered the development of modern biotechnology in the country. The possibility of growth of biotechnology in Brazil is closely related to international leading companies which allocate big amounts to the R&D of new products. However, the greatest part of that R&D takes place in the countries of origin. At present, there is an increase of the demand for biotechnology in Brazil, mostly due to the requirements of the agro-business sector which faces the challenge of providing a increasing domestic market and keeping competitiveness in the international market. Today the country is one of the three greatest worldwide importers of food and has a highly developed agriculture regarding technical and mechanization aspects, and at the same time it has the biggest continental reservoir of cultivable land. Brazil further has competences in genetics and vegetal genetic improvement. Due to that, it is expected that the use of biotechnology shall be critical for reducing costs of production and to increase agriculture competitiveness. At the same time, the country has been also increasing the interaction between teaching and research institutions and the productive sector, thanks to a better articulation of politics and the institutions. The acquisition of biotechnological products and processes is, in the same way as the research which originates them, essentially interdisciplinary and that makes it difficult to perform R&D within the companies which are biotechnology users, even in big companies. That is why there are opportunities arising for technology-based companies which operate in the business-university segment.

## 2. Regulation: Brazilian scenario

There are several laws and legislative instruments which provide a general context for the regulation of this area, which have been elaborated since the nineties. These instruments embrace aspects such as intellectual and industrial property, protection of cultivars, health, access to genetic resources and biosafety, among others. The elements which can be protected in the biotechnology area are: biological matter, the method or process to obtain it, the industrial products which use it, the industrial products obtained through a processes which uses biological matter and industrial products which incorporate it.

The industrial property law broadened patentability to pharmaceutical and food-related processes and products as well as chemical products, and admitted the patentability of microorganisms modified by human intervention, provided the latter fulfill the basic requirements of any patent: novelty, inventive merit and industrial use. The above mentioned law also extended the patent term of protection (up to twenty years) and allowed that workers of public research institutions receive part of the financial benefits derived from the marketing of inventions developed within the scope of the employment relationship.

The law of cultivar protection, on the other hand, sets forth that users of plant varieties must return part of the earnings obtained through the use of said varieties to those who developed them, so that society is always the final beneficiary of technological progress. Together with this act, the National Service of Cultivar Protection (SNPC, according to its Portuguese acronym), was created in the scope of the Ministry of Agriculture, the competent organ for

the protection of cultivars in the whole country. The National Commission of Cultivar Protection was also created (CNPCC, according to its Portuguese acronym), which operates as a consulting and advisory unit for the SNPCC.

## **2.1. GMO Biosafety**

At worldwide level, there are controversies with respect to the environmental safety of transgenic crops, and that also happens with foods containing any genetically modified ingredient. In the case of Brazil, the need to perform environmental impact studies for the release and marketing of transgenic plants has been object of discussion. It is important to mention that said studies constitute estimative projections of future environmental impacts, and not a scientific evaluation of those impacts, reason for which they must be considered as a political instrument of the decision making process.

Out of the twenty-two countries which had biotechnological crops in 2006, half of them were developing countries and the other half, industrialized countries. In a decreasing order of cultivated land, those countries were: United States, Argentina, Brazil, Canada, India, China, Paraguay, South Africa, Uruguay, Philippines, Australia, Romania, Mexico, Spain, Colombia, France, Iran, Honduras, Czech Republic, Portugal, Germany and Slovakia. In that year, the United States, Argentina, Brazil, Canada India and China concentrated 53% of the global area of biotechnology cultivation. However, the growth of the crops of this type was greater in developing countries than in industrialized countries.

In terms of GMO biosafety, Brazil has subscribed the Cartagena Protocol and, at the same time, it has legislation of its own in this area. Since 2005 there is a national law in force which provides safety regulations and control mechanisms of activities involving GMO and their derivatives. This regulation, called the "biosafety act", sets forth a series of provisions and proceedings which must be fulfilled for the development, import, use and marketing of GMO, as well as for the issue of authorizations for the entrance of those products and their derivatives in the country. For the purposes of this act, research activity is that performed in laboratories, under a containment regime or in field, as part of the process for obtaining GMO and their derivatives or their biosafety assessment, which embraces, in the experimental scope, the construction, cultivation, manipulation, transport, transfer, import, export, storage, release into the environment and disposal of GMO and their derivatives. Only public or private law entities can develop activities which involve GMO and their derivatives, which is forbidden for natural persons acting in an autonomous and independent way. In order to conduct research activities in this area, it is necessary to have an authorization of the National Technical Commission of Biosafety (CTNBio, according to its Portuguese acronym), by means of the issue of a biosafety quality certificate. The law also requires the creation of an Internal Biosafety Commission (CIBio, according to its Portuguese acronym) for all the institutions wishing to develop activities with GMO or their derivatives.

Among its functions, the CTNBio sets forth the risk assessment and monitoring criteria of the GMO and their derivatives, individually analyzes the risks of activities and projects on a case-by-case basis, and authorizes and registers research activities in this area. Legislation provides that all of its members must have a PhD degree and a remarkable professional activity in the areas of biosafety, biotechnology, biology, human and animal health and environment. Members are chosen by the Ministry of Science and Technology and they include representatives of national ministries, as well as specialists in the areas of consumer defense, health, environment, biotechnology and science and technology, among others. The first release of a genetically modified organism was authorized by the CTNBio in 2003,

with the permission to market the Roundup Ready soybean produced by Monsanto. The second commercial release authorized by the CTNBio was in 2005, with a cotton crop also produced by Monsanto. The third commercial release was authorized in 2007, for genetically modified corn produced by Bayer. At present, there is a long list of events awaiting CTNBio's approval. The structure of the biosafety national system today is formed by the CTNBio, the National Biosafety Council (CNBS, according to its Portuguese acronym), the registration and monitoring authorities of the ministries of Health, Environment and Agriculture and of the Special Secretariat of Agriculture and Fishery, the Internal Biosafety Commissions (CIBio, according to its Portuguese acronym) and the Biosafety Information System (SIB, according to its Portuguese acronym).

As to food-related biosafety in particular, the legislation sets forth the obligation to label foods derived from GMO. In this respect, the Health Biosafety Commission (CBS, according to its Portuguese acronym) of the Ministry of Health, at the request of the CTNBio, is responsible for evaluating the commercial release requests of genetically modified food, including transgenics. A 2003 decree, on the other hand, regulates the right to information regarding food and ingredients for human or animal consumption containing or produced from genetically modified organisms. Said decree provides that the consumer has to be informed, during marketing, on whether foods contain or are produced from genetically modified organisms, present in a certain percentage over the stipulated limit.

## **2.2. Biodiversity**

Brazil has signed the Convention on Biological Diversity (CBD) of the United Nations, by means of which the country agrees –as the other subscribing countries- to respect the sovereignty of the countries over their genetic patrimony, as well as to allow the access to those resources. Furthermore, the country has rules and regulations in order to avoid the so called “biopiracy”, that is, the unauthorized use of biodiversity resources. Within the national scope, the Federal Constitution expressly protects the diversity and integrity of the genetic resources of the country. There is also a National Congress provision which regulates the Convention on Biological Diversity, creates the Genetic Patrimony Council (CGEN, according to its Portuguese acronym) and provides for the access to genetic resources, the protection and access to the traditional knowledge related thereto, the benefits distribution and access to technology, as well as its transfer in this area. However, the implementation of this provision has been facing difficulties, as it involves several institutions and there are no proper definitions. The CGEN is formed by members of several ministries, associations, public institutions, councils, research institutions and non-governmental organizations. The CGEN is responsible for the access to the genetic resources existing in the country, the distribution of benefits and the exchange and disclosure of the genetic resources and the traditional knowledge related thereto between indigenous and local communities. In March 2006, Brazil hosted the 8<sup>th</sup> International Conference regarding the CBD. That gave the country the opportunity to disclose to the world several Brazilian experiences in biodiversity management and to expose the potential of a sustainable use of biodiversity in the country. Also, the conference allowed to show the political importance of biodiversity for Brazil and for South America as a whole, to promote the execution of projects in favor of Brazilian biodiversity and to give more importance to the interests of the country in international negotiations on biodiversity.

## **2.3. Stem cells and human cloning**

With respect to stem cells, the legislation in force in Brazil allows the use of stem cells obtained from human embryos produced by "in vitro" fertilization for research and therapeutic purposes. The provisions impose some conditions, such as the consent of the parents and the approval by the corresponding ethics committee. The law forbids the trade of embryos and the violation thereof is considered a crime. In fact, this legislation has been target of several objections, from those who consider it "mild" to those who argue the defense of life from its embryonic stage. However, the law constitutes a step which has allowed Brazil not to lose ground in this area with respect to the international context. The competent body on this matter is the National Health Council, which has set forth that the institutions performing research or therapy with human embryonic cells must submit their projects for the evaluation and approval of the respective ethics committees. On the other hand, human cloning is forbidden in Brazil, as in most of the other world countries and as set forth by the United Nations since 2005. Brazilian law prohibits this kind of cloning and provides penalties for those who violate it, ranging from fines to imprisonment. However, biosafety Brazilian law has a contradiction in a critical aspect, as it allows research and therapy with embryonic cells but forbids genetic engineering with human germinal cells, zygotes and human embryos. This fault, attributable to the complexity and novelty of the issue, deserves to be repaired in the light of more consistent technical information or, at least, a greater degree of clarity in the wording of the provision.

## **2.4. Biosafety and environmental impact**

Environmental biosafety assessment of a genetically modified plant variety for agricultural use must take into account the possible influences of the modified plant or the practices related to its cultivation on the environment. Therefore, among the possibility of performing assessments in this area, it is possible to evaluate technologies, their potentialities and possible positive or negative consequences for the conservation not only of the environmental quality but also of the natural resources, thus allowing to select alternatives regarding sustainable development. Legislation regarding the environmental impact in Brazil dates from the beginning of the eighties. In the last years the need to add new evaluations in the biosafety area has arisen due to the advances in the field of biotechnology. That is why the actions developed by the National Program of Biotechnology and Genetic Resources must take into account biosafety regulations and the systematized control mechanisms officialized by the respective law, which provide for the safety of genetically modified organisms, seeking to eliminate the risks for human and animal health and damage to the environment.

Implementation of the biosafety legislation was established as a fundamental condition for the development of R&D projects, including those within the context of international cooperation in this sector. Therefore, it becomes necessary to release information on biosafety and to broaden the bases for a better understanding of the Brazilian legislation and its application. However, there is no Brazilian law which defines what is environmental damage, which represents a contradiction if it is taken into account that there are penalties for this type of damage. There are, on the other hand, rules and regulations for the performance of environmental impact evaluations, which set forth the adoption of a tolerance criterion for impacts of little magnitude.

**Annex IV**  
**Report on Paraguay**

# 1. Introduction

The Paraguayan biotechnological industry shows important progress in issues such as the production of biological products, vaccines for veterinary use and diagnosis kits for bovine diseases, among others. Sectors with an average progress are the cultivation of tissues, plant micropropagation and the cultivation of anthers. However, in sectors such as molecular techniques, use of markers in the genetic analysis of plants, genomics and genetic engineering, progress is scarce or null. There are four laboratories in the country related to activities of agricultural biotechnology research: two of them belong to the National University of Asunción (UNA, according to its Spanish acronym) and the other two, to the Agricultural Research Direction (DIA, according to its Spanish acronym), from the Ministry of Agriculture and Livestock Breeding (MAG, according to its Spanish acronym). For human health purposes, biotechnology is used to develop diagnosis kits and enzyme immunoassays for gluten detection, as well as in the research on leishmaniasis, Chagas' disease and tuberculosis.

Paraguay's main strength for the development of biotechnology is its diversity as a source of genes, which grants it a competitive advantage with respect to other countries. Furthermore, the obstacles which limit the development of biotechnology in the country are the economic and institutional crises, the lack of a science and technology policy and a biotechnology national plan, the low investment in science and technology (both on the part of the State and the private sector) and the lack of relation between private companies and research centers. There is no governmental policy regarding modern agricultural biotechnology and the actions in this area are sectorial.

Transgenic crops appear as a key aspect to be taken into account. Paraguay is an agricultural country, soybean being the main crop, which represents more than 12% of the total production of the country, as measured by its GDP. The soy business exceeded 1.2 millions of hectares in 2006. In 2006, the country achieved the 6<sup>th</sup> position as soybean importer of the world and the 7<sup>th</sup> transgenics producer. Within that context, GM soy constituted 90% of the total surface planted with that crop. Transgenic cotton also progresses in the country: during the cotton campaign of 2007, the segment of transgenic textile crops was of approximately 37,000 hectares, while that dedicated to conventional crops was of near 200,000 hectares.

## 2. Regulation of State areas

The Paraguayan Constitution includes a specific chapter dedicated to the environment protection, which is placed at the same level of importance as the right to life. In terms of biosafety, the constitutional text states that the State "shall regulate the traffic of genetic resources and their technology, protecting national interests". The constitution itself provides the need to regulate the traffic of genetic resources and their technology, tending to protect them from their manipulation until their commercialization.

In the chapter dedicated to health, the Constitution also contemplates aspects related with the regulation of biotechnology, as it sets forth the State obligation to control the quality of

food, chemical, pharmaceutical and biological products, from the manufacturing phase until commercialization. Paraguay has also signed international treaties regarding biotechnology which are part of the domestic legal system, even above the domestic laws. Among those treaties, the Protocol of Cartagena is particularly relevant, as it deals with biosafety, as well as the Convention on Biological Diversity. Additionally, since 1996, the country is a State Party to the International Union for the Protection of New Varieties of Plants.

### **3. Agricultural biotechnology**

The country does not have a specific act governing issues related to transgenic plants. The consequences of the use of transgenic material are analyzed within the general context of the country legislation, through the laws of approval of the Convention on Biological Diversity, the assessment of environmental impact, seeds and protection of cultivars, of vegetal defense, wild life, protected wild areas, the sanitary code and consumer and user defense.

The Research Department in Animal Production (DIPA, according to its Spanish acronym), through the Technical Service Department, is responsible for the records and authorizations regarding food, veterinary medicine and biological products. There is a quality control lab of the samples for each of the three types of products: food, drugs and biological products. The seeds law, on the other hand, regulates the introduction of foreign varieties and sets forth that the Seed National Council is the authority in charge of addressing issues related to propagation materials.

Apart from the above, the National Service of Plants and Seed Quality and Sanity (SENAVE, according to its Spanish acronym), created in 2004 with the mission of supporting the agricultural policy, has the purpose of contributing to the improvement of the quality, phytosanitation and genetic purity conditions of the productive resources, as well as preventing diseases in human beings, animals, plants and the environment. The SENAVE also controls that agricultural supplies comply with legal and statutory regulations. It also has authority to rule on matters related to biotechnology and is the application authority of conventions and agreements on vegetal quality and sanity, seeds and protection of plant varieties and species coming from biotechnology. In that context, the SENAVE elaborates and executes plans, programs and projects that help to the improvement of the quality and phytosanity of vegetal products and subproducts related to the use of biotechnology. The SENAVE acts as technical secretariat of the Biosafety Commission and has a Biotechnology Coordination office which purpose is to address the management of activities related to biotechnology and biosafety.

The Biosafety Commission is the body empowered to authorize the introduction of GMO into the country for agricultural use. It was created in 1997. It is subordinated to the Ministry of Agriculture and Livestock Breeding and the Ministry of Public Health and Social Welfare, and it is formed by representatives of both ministries, of the Secretariat of Environment, of the School of Agricultural Science and non-governmental organizations dedicated to the defense of the environment and related to the biotechnology area. The Commission has powers to record and assess genetically modified material in the country and to authorize their entrance to the national territory.

Furthermore, the Commission has exclusive jurisdiction to control and evaluate the introduction, field tests and release into the environment of genetically modified material, apart from monitoring that the people and institutions working with GMO comply with the security measures. It also monitors and evaluates the security aspects related to GMO, researches their risks and potential benefits and sets forth the measures necessary to order and guarantee the tests that may be required. Any natural or artificial person introducing transgenic material into the country must communicate the event to the Biosafety Commission.

Risk assessment and management under the responsibility of the Biosafety Commission must consider a series of factors which include the characteristics of the ecosystems receiving the GMO tests, the biological characteristics of the organism, the consequences of the potential settlement and persistence of the GMO in the ecosystem and its capacity to transfer genetic material and paths of potential spread, among other aspects. However, there has been a discussion on the need to produce rules and regulations which incorporate in a single instrument the policies, mechanisms and proceedings that must be applied in the process of entrance, evaluation, release into the environment and commercial production of the events of genetic transformation in the interest of the country.

### **3.1. Environmental aspects**

Manipulation, sowing and commercialization of transgenics are activities which may cause alterations in the environment and, therefore, they are attained by the provisions of the law of assessment of environmental impact. These regulations provide the performance of scientific studies which allow to identify and estimate environmental impacts in any work or activity – projected or in progress-, whether they are agricultural exploitations, industrial units or any other. In these cases, projects must be published so that the public and the affected organizations at national, departmental and municipal level may evaluate them, thus protecting industrial secrecy rights and assuring a proceeding which allows the submission of observations, claims and challenges of data on the part of the interested parties.

### **3.2. Intellectual property rights**

Industrial property is protected by the inventions patent law, which protects inventions granting two types of title over industrial property: invention patents and patents of utility models. The application authority is the Industrial Property Direction (DPI, according to its Spanish acronym) of the Ministry of Industry and Trade. Regulations in this area set forth that plants, animals or the biological proceedings to produce them are not patentable. As to agricultural production in particular, the breeder's rights are protected by the Seed and Cultivar Protection Act, the purpose of which is to promote an efficient activity in the production of cultivars, as well as the production, circulation, commercialization and quality control of seeds. Furthermore, the law is oriented to guarantee producers and users in general, the identity and quality of the seed they acquire and to protect the rights of the breeders of new varieties. The law defines as *cultivar* or *variety* the aggregate of cultivated plants, clearly distinguishable from the rest of that species due to morphological, physiological, cytological, chemical or other characteristics, which when reproduced maintain their distinctive features. By means of these provisions, the following varieties and lines of species hereinafter mentioned were protected: cotton, rice, canola, sunflower, corn,

soybean, sorgo and wheat. The producer rights consist in requesting the authorization prior to the production and commercialization of the seed of the protected variety. The granted protection can have a validity of fifteen to twenty years, according to the provisions for each species. Protection of a cultivar does not prevent other people from using it with experimental purposes or for the creation of a new one, which may be registered in the name of its producer without the consent of the producer of the original cultivar, as long as that original variety is not used permanently to produce the new one. The agriculturalist who sows and saves seeds from the protected cultivar for his own use or uses or sells the product obtained from said cultivar as raw material or food does not violate the right of the producer.

### **3.3. Actions from the productive sector**

The agricultural productive sector of Paraguay considers it indispensable to promote biotechnology to increase competitiveness. For that purpose, the Exporters Paraguayan Chamber of Cereal and Oleaginous Plants (CAPECO, according to its Spanish acronym), the Association of Seeds Producers of Paraguay (APROSEMP, according to its Spanish acronym), the Agricultural Coordination of Paraguay (CAP, according to its Spanish acronym), the Production Cooperatives Federation (FECOPROD, according to its Spanish acronym), the Association of Producers of Soybean, Oleaginous Plants and Cereals of Paraguay (APS, according to its Spanish acronym) and the *Central Nacional de Cooperativas UNICOOP Ltda.* created the Institute for the Incorporation of Biotechnology (INBIO). The INBIO is a non-profit civil organization, the purpose of which is to encourage the development of biotechnological research in Paraguay, as well as to promote an adequate access of products derived from agricultural biotechnology into the country and their organized inclusion in the national production.

The entities which participate in the INBIO constitution have stated the need to respond to the legal demands that arise from the present regulatory framework and face the necessary actions and initiatives for the adoption of new technologies which guarantee the technical quality, environmental sustainability and competition conditions of the market for agricultural products. The underlying consideration of this position is that access to new biotechnological products shall be a key factor in order to ensure productive increase and sustainable growth in the long term. A loss of quality of Paraguayan products as a result of technological progress achieved in other countries may seriously affect the economy and competitiveness of Paraguay in the international market.

That is why the above mentioned entities have agreed on a general proposal for transgenic events providers who comply with the regulations required by the laws in force and the international conventions, in order to permit the practical inclusion of technological inventions and to guarantee a mechanism for the payment of royalties or consideration derived from the inclusion of said technology in favor of the company which owns it. In the case of transgenic soy, for instance, the entities agreed upon an insertion and technology payment modality which allocates a percentage of the royalties to be paid to a future Biotechnological Research Fund.

### **3.4. Biodiversity and genetic resources**

Paraguay laws provide that genetic resources belong to the owner of the land in which they are located, although the State may restrain their traffic. The State is in charge of monitoring and executing the phytosanitary control, qualifying and registering land and even -should it be the case- restricting property rights in privately owned protected areas. The Secretariat of Environment (SEAM, according to its Spanish acronym) is responsible for the application of the wild life law, which regulates access, use and conservation of the flora, fauna and biological resources, including native genetic resources. Paraguay has a thorough environmental legislation regarding protected areas and wild life. However, the country does not have a specific legislation to regulate access to the genetic resources in these areas. Furthermore, there are no regulations to protect indigenous property rights over genetic resources. Neither has Paraguay any laws in many other environmental issues, as for instance environmental planning and division into zones and categorization of the use of water. The institutional weaknesses of the country are often shown in the incapacity of public authorities to fulfill their obligations. That entails the failure of their efforts to protect natural resources and the environment, due to a limited political commitment, lack of human and technical resources, and unclear and conflicting responsibilities between management public institutions and the regulation of natural resources.

**Annex III**  
**Report on Uruguay**

# 1. Introduction

Research on vegetal GMO is performed in Uruguay since 1992. The first projects in the country were executed in the context of regional projects and with European financial support and technologies. That was the case of a project by the National Institute of Agricultural Research (INIA, according to its Spanish acronym), entitled "Development of potato cultivars with combined protection against virus and pathogenic fungi", with the participation of scientists from Germany, Argentina, Brazil, Cuba, Spain, France and Uruguay. The project allowed to map and clone genes of that vegetal species, perform field tests in Argentina and Spain (in this last case until the commercial development phase) and generate a research team with the capacity to develop vegetal modified organisms. However, due to the lack of a clear national strategy on biosafety, the project was interrupted, the research group was disassembled, the genes were cloned and the transformed plants were destroyed.

At present, plant genetic transformation activities are developed at the School of Science of the University of the Republic. There is an important research line oriented to the study of the functions of stress-induced genes in *Physcomitrella patens* at the Vegetal Molecular Biology Lab. Works particularly focus to deduce the functions of proteins in abiotic and biotic stress tolerance.

As to GMO with animal and human cells, transgenic mice are produced at the AMSUD Pasteur Institute, which later on are used in cellular and molecular biology studies. There are no specific biosafety regulations for this activity. In the scope of human health, research is performed in the country and there is a very good capacity and development of the production of human recombinant proteins, such as erythropoietin and trombopoietin.

Vaccines present a particular case. The Broadened Immunization Program (PAI, according to its Spanish acronym), that contemplates mandatory and free application of the vaccines necessary in infancy, has vaccines for Hepatitis B, which are prepared by means of genetic engineering techniques. The sale of recombinant vaccines against human papilloma virus is authorized in the country; said virus is the main cause of cancer of the uterus. In accordance with the World Health Organization records, at least 95% of these cancers contain DNA of the virus.

With respect to transgenic crops, at present there are three events being traded within the country: one of soy and two of corn. Glyphosate-resistant transgenic soy was introduced in Uruguay in 1999 and thanks to that the area dedicated to this crop increased significantly. At present, soy is the main crop of the country and continues its ongoing expansion since agricultural year 2000/2001. In the last harvest, the crop reached an area of approximately 447 thousand hectares, with a production of near 800 thousand tons. Almost the totality of the soy sowed in Uruguay is genetically modified. As to corn events, both have an insecticide protein. The second event is also herbicide-resistant. In September 2006, pursuant to the Cultivar National Registry, there were one hundred corn cultivars authorized to be traded for grain, which represented more than half the corn seeds supply of all the country. For that year, transgenic corn represented 40% of the total area of this crop.

## 2. GMO regulation

The biotechnology regulatory system involves different governmental institutions. The Ministry of Livestock Breeding, Agriculture and Fishery (MGAP, according to its Spanish acronym) has jurisdiction over the agricultural, agrochemical, seed-related and veterinary aspects; as to the latter, the regulations for the MERCOSUR are applied, although the Uruguayan laws set forth more strict requirements than those agreed upon in the region. Environmental issues are within the scope of the Ministry of Dwelling, Territorial Organization and Environment (MVOTMA, according to its Spanish acronym). Human health is under the responsibility of the Ministry of Public Health, which is empowered to pass regulations on medication, food and environmental health control. The Environment National Direction, on the other hand, is responsible for the elaboration, execution, supervision and evaluation of the national plans of environmental protection and for proposing and incrementing the national policy on this matter.

With respect to biosafety, Uruguay has focused mainly in GMO and, within these organisms, the resulting regulations have been related to plants. In 1991, a Biotechnology Unit was created at the INIA and the issue was included in the working plan of the institution, thus enabling contacts with several institutions. By that time, the first works of genetic engineering research and development of human and material capacities started to be performed, which later on gave rise to international projects, graduation theses and special assignments at the University of the Republic.

Uruguay ratified the UN Convention on Biological Diversity in 1993. That same year, the MGAP and the INIA technicians started to warn on the development on transgenic plants and, consequently, on the need to create a working commission on the matter. That derived in the creation of a Risk Assessment Commission within the scope of the National Direction of Agricultural Services (DGSA, according to its Spanish acronym) of the MGAP. In fact, a little later on, the first applications for introducing herbicide-resistant GM soy events into the country were received, followed by other requests regarding insect-resistant corn; later on, other types of transformations and species followed, which included herbicide-tolerant corn, rice and eucalyptuses.

In year 2000 the Genetically Modified Plants Risk Assessment Commission (CERV, according to its Spanish acronym) was created as advisory authority of the Executive Power. The Commission performance generated a scope for the analysis, treatment and management of requests for approval of GMO, from their testing phase until their release into the environment. The CERV's creation decree set forth the need to have proceedings to authorize the introduction, use and manipulation of plants and their genetically modified parts. It further set forth the need to conduct risk assessments on scientific basis, considering their impact in the environment and in the biological diversity in particular, also taking into account eventual effects on human and animal health and vegetal sanity. The Commission is formed by specialists from the MGAP, the MVOTMA, the Ministry of Public Health, the Seed National Institute and other institutions specialized in the area.

The regulations provide that every time the MGAP or the INASE receive a request for the import or any other type of action with GMO, the competent authorities request that the interested party forwards information signed by the legal and technical representatives for the introduction of small amounts, their characteristics, regarding both the organism and the molecular biology of the donor-receptor-vector system used for the production of the genetically modified plant, the place where they have all been produced, a detailed description of the goals of the introduction and, above all, the detailed description of the biosafety methods and proceedings used in other countries, the use of which is proposed in Uruguay. Should it be the case, details regarding the destination of the grown products are also requested, as well as details as to the destination of the products, the plots of land used,

their future uses and subsequent controls and the emergency plans in case of escapes possibilities. The information is then forwarded to the CERV for processing.

Another act of year 2000, in a section specifically referring to biosafety, states that the MVOTMA shall issue regulations and apply the measures necessary to prevent and control environmental risks derived from the creation, manipulation, use or release of genetically modified organisms as a result of biotechnological applications while they can affect the conservation and sustainable use of the biological diversity and the environment.

### **3. National biosafety framework**

The Environment National Direction (DINAMA, according to its Spanish acronym) of the MVOTMA, national competent authority in terms of environmental protection, implemented the project for the Development of Uruguay's Biosafety National Framework (MNBS, according to its Spanish acronym). The project execution had the active participation of the actors directly involved on the matter, which was effected through the Coordination National Committee (CNC) and was supplemented with the integration of working groups and disclosure conferences.

One of the main results of the project was the education and release of information in several levels of the population, materialized in the organization of the existing information and the elaboration of diagnoses regarding the national situation of biosafety and live modified organisms. Additionally, that information was released within the participant institutions, including the matter in the public agenda. In accordance with the final report of the project, it did not elaborate concrete regulatory instruments, although there were recommendations to improve the regulatory framework in force for some scopes of application (research, industry, animal live modified organisms) where it is rather deficient.

As to the veterinary area, the regulation is under the responsibility of the MGAP. Anyway, the rules and proceedings refer to biosafety regarding non genetically modified organisms, and they focus in sanitary issues so as to avoid the dissemination of diseases in the animal stock and in human beings. To date, only one recombinant imported vaccine has been approved to be applied in small animals. Authorizations of recombinant vaccines for animals are analyzed and approved on a case-by-case basis.

Regarding human and environmental health, the regulation respectively corresponds to the Ministries of Public Health and the MVOTMA. As to human health, there is research being developed and human recombinant proteins such as erythropoietin and trombopoietin are produced. Biosafety aspects are also considered for organ and tissue xenotransplantation purposes. In the environmental area, there are general regulations regarding effluents and residues, although without a specific definition in the area of products derived from biotechnology.

### **4. GMO Intellectual Property**

In Uruguay, there are statutory and legal provisions regarding the registration, use and exploitation of invention patents, utility models and industrial designs. The National Constitution enshrines the general protection of the right to enjoy labor and property, and it further sets forth that "intellectual labor and copyrights of the inventor or the artist shall be recognized and protected by the law". Additionally, Uruguay has been a party to several agreements and conventions in intellectual property matters, such as the Paris Convention (1961), the Uruguay Round of the General Agreement on Tariffs and Trade – GATT (1986-1993), the Agreement of Jardín de las Rosas (1991) and the Convention on Biological Diversity of Rio de Janeiro (1992). An act of 1999 regulates the rights and obligations regarding invention patents, utility models and industrial designs. The registration proceedings are executed by request to the Industrial Property National Direction, depending on the Ministry of Industry and Power.

The law of patents, utility models and industrial designs defines as patentable those new inventions of products or proceedings which imply an inventive activity and are susceptible of industrial use. The following, among others, are not considered inventions: findings, scientific theories and mathematical methods, animals or plants –except for microorganisms and the essentially biological proceedings for the production of plants or animals. Neither are patentable the diagnosis, therapeutic or surgical methods for the treatment of humans or animals.

The seeds law passed in 1997 provides for the protection in this area for a period between fifteen and twenty years, according to the considered species. All cultivars of genetically modified species authorized for trade are registered with the INASE. The term *cultivar* refers to an aggregate of cultivated plants which can be distinguished from the rest of its species by any characteristic (morphological, physiological, cytological, chemical or other) and when sexually or asexually reproduced they keep characteristics of their own. When used to refer to a grown variety, the term "variety" is equivalent to the term "cultivar". The Executive Power may declare a property deed for the "public use" for a period of no longer than two years by means of a prior and fair compensation to the owner, should it understand that disposing of the product obtained from the cultivation is in the general interest.

The right over a vegetal material is granted provided the requirements of novelty are complied with (that is, not offered for sale or traded with the consent of the breeder) and further provided the protection request is submitted, with respect to -at least- one morphological, physiological, cytological, chemical or other important characteristic, non-fluctuating and susceptible of being accurately described and recognized. Furthermore, the material must be homogeneous enough in the aggregate of its characteristics, according to its reproduction or multiplication system, it must remain stable in its essential characteristics (that is to say that at the end of every multiplication cycle executed in the indicated manner by its producer, it shall keep the characteristics whereby he defined it) and must have received a denomination acceptable for registration according to what is set forth by the rules and regulations.

The term of validity of the property deed is in force from the moment of its temporary issue, and shall not be shorter than fifteen years nor longer than twenty, according to the considered species and the regulations. The deed registered with the Cultivar Property Registry enables the owner to engage in every legally admissible business, thus conferring him the exclusive right or the submission for his previous authorization for the sale, trade within the country or abroad or donation, pursuant to this law and its regulations of the sexual reproduction or vegetative multiplication in his capacity as owner of the cultivar in issue.

The property deed of a cultivar may be revoked or expire, among other reasons, due to the end of the homogeneity and stability conditions, at the INASE request or whenever the

bearer is not capable of providing the reproduction material which allows to produce the cultivar as agreed upon at the moment of granting the title.